



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDE
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 1/21/10

SUBJECT: Abamectin; Bridging Studies Supporting Foliar Application Uses of New SC Formulations. Summary of Analytical Chemistry and Residue Data.

PC Code: 122804

DP Barcodes: 364734, 364737

Decision Nos.: 407406, 407407

Registration Nos.: 100-RGLR and 100-RGLN

Petition No.: NA

Regulatory Action: Product registration

Risk Assessment Type: NA

Case No.: NA

TXR No.: NA

CAS No.: 71751-41-2

MRID No.: See MRID Summary Table

40 CFR: 180.449

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MRID Summary Table		
MRID No.	Study Type	Comments
47702803	860.1500 Pome fruits	New DER; 47702803.der.doc
47702804	860.1500 Cucurbit vegetables	New DER; 47702804.der.doc
47702805	860.1500 Leafy vegetables	New DER; 47702805.der.doc
47702806	860.1500 Fruiting vegetables	New DER; 47702806.de1.doc
	860.1520 Tomato processing	New DER; 47702806.de2.doc
47702807	860.1500 Citrus fruits	New DER; 47702807.der.doc

This document was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B; Durham, NC 27713). The document has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

Executive Summary

Abamectin includes the combined residues of avermectin B₁ [a mixture of avermectins containing $\geq 80\%$ avermectin B_{1a} (5-*O*-demethyl avermectin A₁) and $\leq 20\%$ avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A₁)] and its delta-8,9-isomer. Abamectin is a natural fermentation product of the soil bacterium *Streptomyces avermitilis*. It is used as an insecticide/miticide on crops for the control of mites, leafminers, and other insects, as a seed protectant against nematodes, and in veterinary medicine for treatment of internal and external parasites and mites.

Tolerances have been established for the combined residues of avermectin B₁ (a mixture of avermectins containing $\geq 80\%$ avermectin B_{1a} and $\leq 20\%$ avermectin B_{1b}) and its delta-8,9-isomer in/on various plant and livestock commodities at levels ranging from 0.005 ppm to 0.20 ppm (40 CFR §180.449).

Syngenta Crop Protection currently markets several 0.15 lb active ingredient (ai)/gal emulsifiable concentrate (EC) formulations of abamectin that are registered for repeated foliar applications for the control of mites and selected insects on the following crops: almonds, walnuts, apples, pears, avocados, celeriac, citrus fruits, cotton, cucurbit vegetables, fruiting vegetables, grapes, herbs (except chives), hops, leafy vegetables, mint, plums, prunes, potatoes and strawberries. Application rates for the EC formulations on these crops range from 0.014-0.023 lb ai/A, with minimum retreatment intervals (RTIs) of 7 to 30 days, and maximum seasonal use rates of 0.038-0.075 lb ai/A/season. Depending on the crop, the EC formulations may be applied using only ground equipment or by ground and aerial equipment. The preharvest intervals (PHIs) range from 7-28 days, with the exception of strawberry, which has a 3-day PHI.

Syngenta is requesting the registration of two new suspension concentrate (SC) formulations for abamectin. One is a single active ingredient formulation containing 8.0% abamectin (0.7 lb ai/gal SC; Agri-Mek SC Miticide/ Insecticide; EPA Reg. No. 100-RGLR), and the other is a multiple active ingredient (MAI) formulation (Agri-Flex™ Miticide/Insecticide, EPA Reg. No. 100-RGLN) containing 3.0% abamectin (0.277 lb ai/gal) and 13.9% thiamethoxam (1.27 lb ai/gal). The 0.7 lb ai/gal SC formulation is proposed for repeated foliar applications on all the crops currently listed on the EC labels, with the exception of strawberry. The proposed use directions for the 0.7 lb ai/gal SC label are identical to the respective crops on the EC labels in terms of timing, application rate, minimum PHI, and other use restrictions. The only difference is that the label for the 0.7 lb ai/gal SC requires the addition of a horticultural oil or surfactant to the spray mix for applications to all crops. The MAI formulation is proposed for repeated foliar applications only on apples, pears, citrus fruits and grapes, and the use rates for abamectin are lower on the label for the MAI formulation than on the label for the 0.7 lb ai/gal SC.

Syngenta is requesting that the available residue data and existing tolerances supporting the foliar uses of the EC formulation of abamectin be translated to support the same uses for the new SC formulations as residue levels in/on crops are similar between the EC and SC formulations at PHIs of ≥ 7 days when an adjuvant is included in the spray mix for the SC formulations. To support their position, Syngenta submitted full-scale field trials reflecting use of the 0.7 lb ai/gal SC formulation on the representative crops from the following crop groups: leafy vegetables, cucurbit vegetables, fruiting vegetables, citrus fruits and pome fruits.

The submitted field trials on head and leaf lettuce, spinach, celery, cucumbers, squash, cantaloupes, tomatoes, peppers, oranges, lemons, grapefruit, apples and pears are adequate. An adequate number of field trials were conducted on each crop in the appropriate geographic regions using the 0.7 lb ai/gal SC formulation of abamectin at the proposed 1x rates, and all applications included the use of either a horticultural oil or a non-ionic surfactant (NIS), in accordance with the label directions. The appropriate RAC samples were collected at the proposed PHI for each crop, and samples were analyzed using acceptable data collection methods.

Following repeated foliar applications of the 0.7 lb ai/gal SC formulation at 1x the proposed rate, the combined residues of abamectin (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) were <0.004-0.062 ppm in/on all samples of leafy vegetables harvested 7 days after treatment (DAT), <0.004-0.011 ppm in/on all fruiting vegetables harvested at 7 DAT, <0.004 ppm in/on all cucurbit vegetables harvested at 7 DAT, <0.004-0.008 ppm in/on all citrus fruits harvested at 7 DAT, and <0.004-0.011 ppm in/on all apples and pears harvested at 28 DAT. For each crop tested, the residues resulting from application of the SC formulation were well below the current tolerances for abamectin residues in/on leafy vegetables (0.10 ppm), fruiting vegetables (0.02 ppm), cucurbit vegetables (0.005 ppm), citrus fruits (0.02 ppm), apples (0.02 ppm), and pears (0.02 ppm).

Regulatory Recommendations

The available field trial data directly support the proposed uses of the SC formulations (Agri-Mek SC Miticide/ Insecticide, EPA Reg. No. 100-RGLR and Agri-Flex™ Miticide/Insecticide, EPA Reg. No. 100-RGLN) on leafy vegetables, fruiting vegetables, cucurbit vegetables, citrus fruits, and pome fruits, and indicate that the current tolerances on these crops or crop groups are adequate. In addition, because abamectin residues resulting from use of the SC formulation were well below the current tolerances for each of these representative crops, HED will translate the existing residue data from the EC formulation of abamectin to support identical uses for the SC formulation, provided that use directions for the SC formulation always require the use of a non-ionic surfactant or a horticultural oil in the spray mix and the PHIs are ≥ 7 days.

The proposed SC labels (Agri-Mek SC Miticide/ Insecticide, EPA Reg. No. 100-RGLR and Agri-Flex™ Miticide/Insecticide, EPA Reg. No. 100-RGLN) must be revised so that the label use directions match the available field trials regarding type and amount of surfactant. Since either a non-ionic surfactant or a horticultural oil was used in the SC field trials, the adjuvant specified in the Directions for Use for each crop on the SC labels must be a non-ionic surfactant and/or a horticultural oil. (The general term "surfactant" is not adequate since all types of surfactants were not tested.) Also, the amount (v/v) of the

non-ionic surfactant and/or crop oil must be specified in the Directions for Use for each crop on the SC labels and must be within the range of the amount (v/v) used in the SC field trials.

No new abamectin tolerances are required to support use of the SC formulations (Agri-Mek SC Miticide/ Insecticide, EPA Reg. No. 100-RGLR and Agri-Flex™ Miticide/Insecticide, EPA Reg. No. 100-RGLN). Also, use of the SC formulations will not increase the Estimated Drinking Water Concentrations for abamectin (DP#'s 365084 and 365086, Ibrahim Abel-Saheb, Ph.D., 10/15/09). Therefore, a new Human Health Risk Assessment for abamectin is not required for these registration requests.

Residues of thiamethoxam from use of Agri-Flex™ Miticide/Insecticide (EPA Reg. No. 100-RGLN) are under concurrent review.

Background

Abamectin includes the combined residues of avermectin B₁ [a mixture of avermectins containing $\geq 80\%$ avermectin B_{1a} (5-*O*-demethyl avermectin A₁) and $\leq 20\%$ avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A₁)] and its delta-8,9-isomer. Abamectin is a natural fermentation product of the soil bacterium *Streptomyces avermitilis* and is used for the control of mites, leafminers, and other insects on various crops, as a seed protectant against nematodes, and in veterinary medicine for treatment of internal and external parasites and mites.

Adequate residue data are currently available supporting the use of EC formulations of abamectin for foliar applications to the following crops: almonds, walnuts, apples, pears, avocados, celeriac, citrus fruits, cotton, cucurbit vegetables, fruiting vegetables, grapes, herbs (except chives), hops, leafy vegetables, mint, plums, prunes, potatoes and strawberries.

Syngenta has subsequently developed a new SC formulation of abamectin and conducted limited side-by-side field trials on lettuce, spinach and tomatoes (2 tests each) at three locations to demonstrate that residues resulting from the two formulations would be comparable on these representative crops at 0 and 7 DAT. However, the results from these limited field trials (data not submitted) indicated that abamectin residues were generally higher following foliar applications of the SC formulation than for the EC formulation. As the primary route of degradation of abamectin is through photodegradation, Syngenta theorized that the photodegradation of the abamectin in the SC formulation was reduced due to the light scattering properties of the larger particles present in the SC formulation and the decreased dispersion of the chemical across the leaf surface. In subsequent tests on lettuce (not submitted), residues resulting from foliar application of the EC and SC formulations were again compared over 0-21 days post-treatment. However, for these tests, the particle size for the SC formulation was reduced from 1-3 μm to 0.5 μm and the formulations were compared with and without the addition of a surfactant to increase the dispersion of the SC formulation. The results indicated that abamectin residues were comparable between the EC and SC formulation when the particle size in the SC formulation was reduced and a surfactant was included in the spray mix.

Based on these preliminary tests, Syngenta conducted full-scale field trials on selected crops using the SC formulation, with an adjuvant, in order to demonstrate that residues resulting from the SC formulations would be comparable to the EC formulation for crops with PHIs of ≥ 7 days. The crops selected for the field trials reportedly cover the major uses of abamectin and included a range of PHIs. This report addresses only issues relevant to the comparison of the EC formulation with the proposed SC formulations. Other residue chemistry requirements for abamectin are addressed in the original reviews for the foliar uses for the EC formulation. The chemical structure and nomenclature of abamectin and the physicochemical properties of the technical grade of abamectin are presented in Tables A.1 and A.2.

TABLE A.1. Test Compound Nomenclature.

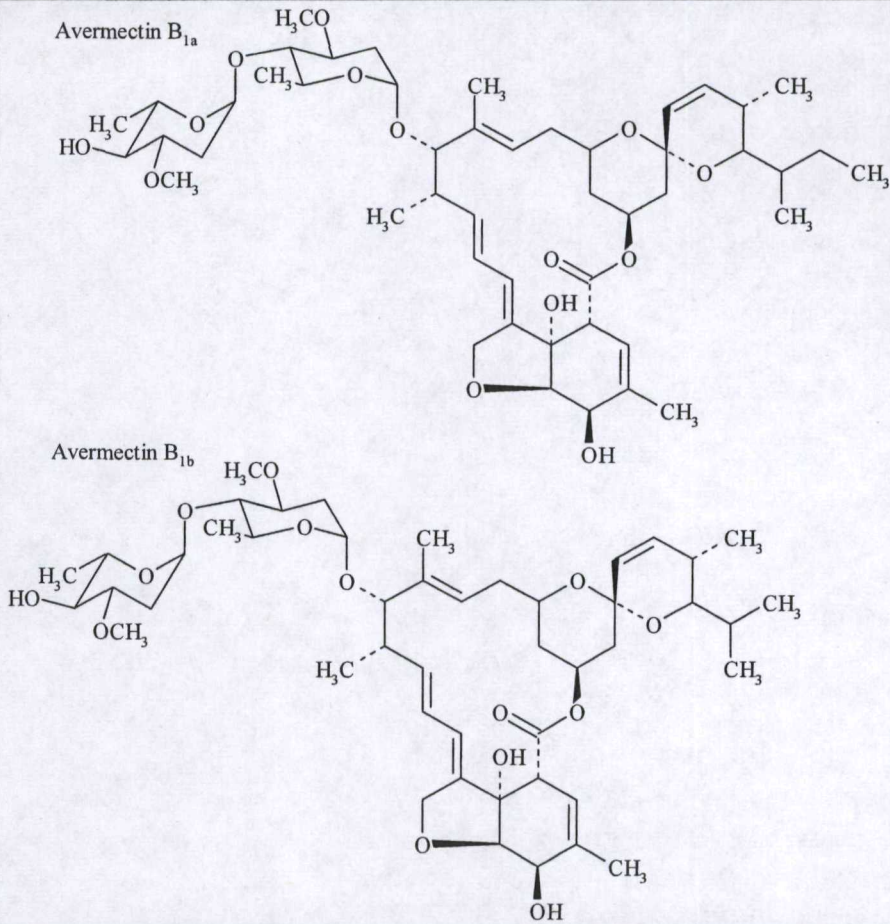
Compound	 <p>Avermectin B_{1a}</p> <p>Avermectin B_{1b}</p>
Common name	Abamectin; Avermectin B ₁
Company experimental name	MK-0936
IUPAC name	mixture of (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> ,22 <i>Z</i>)-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i>)-6'-[(<i>S</i>)- <i>sec</i> -butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 ^{4,8} .0 ^{20,24}]pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-4- <i>O</i> -(2,6-dideoxy-3- <i>O</i> -methyl- α -L-arabino-hexopyranosyl)-3- <i>O</i> -methyl- α -L-arabino-hexopyranoside and (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> ,22 <i>Z</i>)-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i>)-21,22-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 ^{4,8} .0 ^{20,24}]pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-4- <i>O</i> -(2,6-dideoxy-3- <i>O</i> -methyl- α -L-arabino-hexopyranosyl)-3- <i>O</i> -methyl- α -L-arabino-hexopyranoside
CAS name	Avermectin B ₁
CAS registry number	71751-41-2

TABLE A.1. Test Compound Nomenclature.

End-use products (EPs)	0.15 lb ai/gal EC (Agri-Mek 0.15EC Miticide/Insecticide; EPA Reg. No. 100-898) 0.7 lb ai/gal SC (Agri-Mek SC Miticide/Insecticide; EPA Reg. No. 100-RGLR) 0.277 lb ai/gal SC (Agri-Flex SC Miticide/Insecticide; EPA Reg. No. 100-RGLN) ¹
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¹ This product is an MAI which also contains 1.27 lb/gal of thiamethoxam.

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound Abamectin.

Parameter	Value	Reference
Melting point/range	161.8-1.69.4°C	Study report (MRID 47702806)
pH	8-9 at 25°C	
Density	1.18 x 10 ³ kg/m ³ at 22°C	
Water solubility at 25 °C	1.21 µg/mL at pH 7.57	
Solubility in organic solvents	Acetone 72 g/L	
	Dichloromethane 470 g/L	
	Ethyl acetate 160 g/L	
	Hexane 0.110 g/L	
	Methanol 13 g/L	
	Octanol 83 g/L	
	Toluene 23 g/L	
Vapor pressure at 25 °C	<3.7 x 10 ⁻⁶ Pa	
Dissociation constant (pK _a)	no dissociation constant in aqueous solution	
Octanol/water partition coefficient, Log P	4.4 at pH 7.2	
UV/visible absorption spectrum	Absorbance maxima	
	Neutral : 32,549 l/mol•cm at 245 nm	
	18,983 l/mol•cm at 255 nm	
	Acidic: 34,515 l/mol•cm at 245 nm	
	20,977 l/mol•cm at 255 nm	
	Basic: 29,551 l/mol•cm at 245 nm	

860.1200 Directions for Use

Syngenta currently has three abamectin formulations registered for foliar application uses on food/feed crops. All three formulations are 0.15 lb ai/gal EC formulations. One is registered for use only on cotton (Zephyr 0.15 EC Miticide/Insecticide; EPA Reg. No. 100-897), and the other two EC formulations are both registered for use on a wide variety of crops (Agri-Mek 0.15 EC Miticide/Insecticide; EPA Reg. No. 100-898, and EPI-Mek 0.15 EC Miticide/Insecticide; EPA Reg. No. 100-1154). These two formulations include uses on the following crops: almonds, walnuts, apples, pears, avocados, celeriac, citrus fruits, cotton, cucurbit vegetables, fruiting vegetables, grapes, herbs (except chives), hops, leafy vegetables, mint, plums, prunes, potatoes and strawberries.

Syngenta is requesting the registration of two new SC formulations for abamectin. One is a single active ingredient formulation containing 8.0% abamectin (0.7 lb ai/gal SC; Agri-Mek SC Miticide/Insecticide; EPA Reg. No. 100-RGLR). This formulation is being proposed for use on all crops currently on the label for the 0.15 lb ai/gal EC (EPA Reg. No. 100-898), with the exception of strawberries. The other SC formulation is a MAI formulation (Agri-Flex™ Miticide/Insecticide, EPA Reg. No. 100-RGLN) containing 3.0% abamectin (0.277 lb ai/gal) and 13.9% thiamethoxam (1.27 lb ai/gal). This formulation is being proposed for use only on apples, pears, citrus fruits and grapes.

Example labels for the two new SC formulations were provided and are summarized below in Table 3. For comparison, the use directions on the most recently approved label for the main 0.15 lb ai/gal EC formulation (EPA Reg. No. 100-898, approved 5/16/08) are also summarized in Table 3.

Table 3. Summary of Directions for Use of Abamectin EC and SC Formulations.						
Applic. Timing, Type, and Equip. ¹	Formulation [EPA Reg. No.]	Max. Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations ^{6,7}
Almonds/Walnuts ²						
Broadcast foliar applications when pests are present; ground application only	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.023	2	0.047	21	Use in combination with a horticultural oil (0.25% v/v or 1 gal/A). Apply in a minimum volume of 40 gal/A. The minimum RTI is 21 days. Do not allow livestock to graze in treated orchards.
Apples ²						
Broadcast foliar applications after petal fall; ground application only	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.023	2	0.047	28	Use in combination with a horticultural oil (0.25% v/v or 1 gal/A). Apply in a minimum volume of 40 gal/A. The minimum RTI is 21 days. Do not allow livestock to graze in treated orchards.
	0.277 lb ai/gal SC [100-RGLN]	0.018	2	0.037	35	
Avocados						
Broadcast foliar applications when pests are present; ground or aerial applications	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.023	2	0.047	14	Use in combination with a horticultural oil (1-4% v/v), and apply in a minimum volume of 50 gal/A by air or 100 gal/A by ground. The minimum RTI is 30 days. Do not allow livestock to graze in treated orchards.
Celeriac ²						
Broadcast foliar applications when pests are present; ground applications only	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.019	3	0.056	7	Use in combination with a NIS and apply in a minimum volume of 20 gal/A. The minimum RTI is 7 days. For resistance management, do not make more than 2 sequential applications.
Citrus Fruits ²						
Broadcast foliar applications when pests are present; ground or aerial application ³	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.023	3	0.047	7	Use in combination with a horticultural oil (0.2-1.0 v/v). For aerial applications apply in a minimum volume of 10 gal/A. The minimum RTI is 30 days. Do not allow livestock to graze in treated orchards.
	0.277 lb ai/gal SC [100-RGLN]	0.018	3	0.037	7	
Cotton						
Broadcast foliar applications when pests are present; ground or aerial applications	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.019	Not specified (NS)	0.038	20	Use in combination with a NIS and apply in a minimum volume of 5 gal/A. The minimum RTI is 21 days. Do not feed or allow livestock to graze treated cotton.
Cucurbit Vegetables						

Table 3. Summary of Directions for Use of Abamectin EC and SC Formulations.

Applic. Timing, Type, and Equip. ¹	Formulation [EPA Reg. No.]	Max. Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations ^{6,7}
Broadcast foliar applications when pests are present; ground or aerial application ⁴	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.019	NS	0.056	7	Use in combination with a surfactant ⁵ and apply in a minimum volume of 20 gal/A by ground and in 5 gal/A aerially. The minimum RTI is 7 days. Do not make more than 2 sequential applications.
Fruiting Vegetables						
Broadcast foliar applications when pests are present; ground or aerial application ⁴	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.019	NS	0.056	7	Use in combination with a surfactant ⁵ and apply in a minimum volume of 20 gal/A by ground and in 5 gal/A aerially. The minimum RTI is 7 days. Do not make more than 2 sequential applications.
Grapes						
Broadcast foliar applications when pests are present; ground applications only	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.019	2	0.038	28	Use in combination with a NIS, and apply in a minimum volume of 50 gal/A using conventional ground equipment or in 5 gal/A using electrostatic sprayers. The minimum RTI is 21 days. Do not allow livestock to graze in treated vineyards.
	0.277 lb ai/gal SC [100-RGLN]	0.012	2	0.024	28	
Herb Crop subgroup (except chives)						
Broadcast foliar applications when pests are present; ground applications only	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.019	3	0.056	14	Use in combination with a NIS ⁵ , and apply in a minimum volume of 30 gal/A. The minimum RTI is 7 days. Do not make more than 2 applications per cutting (harvest).
Hops (not approved for use in CA) ²						
Broadcast foliar applications when pests are present; ground applications only	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.019	2	0.038	28	Use in combination with a NIS ⁵ , The minimum RTI is 21 days. Do not allow livestock to graze in treated hops yards.
Leafy Vegetables						
Broadcast foliar applications when pests are present; ground or aerial application ⁴	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.019	NS	0.056	7	Use in combination with a NIS ⁵ and apply in a minimum volume of 20 gal/A by ground and in 5 gal/A aerially. The minimum RTI is 7 days. Do not make more than 2 sequential applications.
Mint						
Broadcast foliar applications when pests are present; ground or aerial application ⁴	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.014	3	0.042	28	Use in combination with a surfactant ⁵ and apply in a minimum volume of 20 gal/A by ground and in 5 gal/A aerially. The minimum RTI is 7 days. Do not make more than 2 sequential applications. Do not allow livestock to graze or feed treated foliage to livestock.
Pears ²						
Broadcast foliar applications when pests are present; ground application	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.023	2	0.047	28	Use in combination with a horticultural oil (0.25% v/v or 1 gal/A). Apply in a minimum volume of 40 gal/A. The minimum RTI is 21 days. Do not

Table 3. Summary of Directions for Use of Abamectin EC and SC Formulations.

Applic. Timing, Type, and Equip. ¹	Formulation [EPA Reg. No.]	Max. Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations ^{6,7}
only	0.277 lb ai/gal SC [100-RGLN]	0.018	2	0.037	35	allow livestock to graze in treated orchards.
Plums and Prunes ²						
Broadcast foliar applications when pests are present; ground application only	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.023	2	0.047	21	Use in combination with a NIS or horticultural oil (0.25% v/v or 1 gal/A). Apply in a minimum of volume 40 gal/A. The minimum RTI is 21 days. Do not allow livestock to graze in treated orchards.
Potatoes						
Broadcast foliar applications when pests are present; ground or aerial application ⁴	1.5 lb ai/gal EC [100-898] 0.7 lb ai/gal SC [100-RGLR]	0.019	3	0.056	14	Use in combination with a surfactant and apply in a minimum volume of 20 gal/A by ground and in 5 gal/A aerially. The minimum RTI is 7 days. Do not make more than 2 sequential applications.
Strawberries						
Broadcast foliar applications when pests are present; ground equipment only	1.5 lb ai/gal EC [100-898]	0.019	NS	0.075	3	Apply in a minimum volume of 50 gal/A using conventional ground equipment or in 10 gal/A using an electro-static sprayer. The minimum RTI is 21 days. Do not make more than 2 sequential applications.

¹ Do not apply through any type of irrigation system.

² Dilute or concentrated spray volumes can be used for applications to almonds, walnuts, apples, celeriac, citrus fruits, hops, pears, and plums/prunes.

³ Aerial applications on citrus are permitted on the SC labels only for the control of citrus leaf miner. However, aerial applications to citrus are not allowed in CA or on the EC label.

⁴ Aerial applications are not allowed in NY.

⁵ On the label for the 1.5 lb ai/gal EC, the use of a surfactant is optional for applications to cucurbit vegetables, fruiting vegetables, herbs, hops, leafy vegetables and mint.

⁶ Adjuvant Requirement: To avoid illegal crop residues, the SC formulations **must always** be mixed with an adjuvant as specified in the **Directions for Use** for each crop on this labels.

⁷ Spray Drift: Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment and weather related factors determine the potential for spray drift. The applicator is responsible for considering all of these factors when making application decisions.

Conclusions. The use directions for the 0.7 lb ai/gal SC formulation are identical to the same crop uses currently registered for the 0.15 lb ai/gal EC formulation, with the following two exceptions: (1) SC formulation requires use of a horticultural oil or surfactant in the spray mix for all uses; and (2) the SC formulation does not include a use on strawberries, which have a PHI of < 7 days (3-day PHI). The use rates for abamectin on the MAI SC label (the formulation containing 0.277 lb/gal of abamectin) are lower than for the same uses on the 0.7 lb ai/gal SC label.

The proposed SC labels (Agri-Mek SC Miticide/ Insecticide, EPA Reg. No. 100-RGLR and Agri-Flex™ Miticide/Insecticide, EPA Reg. No. 100-RGLN) must be revised so that the label use directions match the available field trials regarding type and amount of surfactant. Since either a non-ionic surfactant or a horticultural oil was used in the SC field trials, the adjuvant specified in the Directions for Use for each crop on the SC labels

must be a non-ionic surfactant and/or a horticultural oil. (The general term "surfactant" is not adequate since all types of surfactants were not tested.) Also, the amount (v/v) of the non-ionic surfactant and/or crop oil must be specified in the Directions for Use for each crop on the SC labels and must be within the range of the amount (v/v) used in the SC field trials.

860.1340 Residue Analytical Methods

Adequate methods are available for enforcing tolerances of abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) in/on plant and livestock commodities. These methods are high performance liquid chromatography/fluorescence detection (HPLC/FLD) methods which have LOQs of ≤ 0.01 ppm for each analyte. These methods determine residues of avermectin B_{1a} and its 8,9-Z isomer as a single component.

Samples from the submitted field trials were analyzed for abamectin residues using either a HPLC/FLD method or a liquid chromatography/tandem mass spectrometry (LC/MS/MS) method. The HPLC/FLD method (Novartis Method No. M-073.1; "HPLC-Fluorescence Method for the Quantitation of Avermectin B₁ and 8,9-Z Avermectin B₁ in/on Fruits and Vegetables") is similar to the current tolerance enforcement methods. The LC/MS/MS method (Morse Analytical Method No. Meth-192/revision 2; "Determination of Abamectin Residues in Fruits and Vegetables (Raw Agricultural Commodity) by LC/MS/MS"), utilizes the same sample extraction and purification procedures as the HPLC/FLD method, but does not include a derivatization step and uses MS/MS detection for analysis.

For both methods, abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) were extracted with acetonitrile:0.1% phosphoric acid (25:75). Residues were partitioned into hexane, dried over anhydrous Na₂SO₄, and purified by elution through an aminopropyl solid phase extraction (SPE) cartridge with ethyl acetate:methanol (72:25, v/v). Residues were then concentrated to dryness and redissolved in acetonitrile for HPLC/FLD or LC/MS/MS analysis.

For Method M-073.1, the purified residues of all three analytes were derivatized with trifluoroacetic anhydride, and the resulting derivatized residues were analyzed by HPLC/FLD using a reverse phase C₈ column and an isocratic mobile phase of acetonitrile:water (85:15, v/v). For this method, the derivatized residues of avermectin B_{1a} and 8,9-Z avermectin B_{1a} are determined as a single component, and avermectin B_{1b} is determined separately. The validated LOQ for this method is 0.002 ppm for each analyte.

For Method Meth-192/Revision #2, no derivatization step was required. The purified residues were analyzed by LC/MS/MS using a reverse phase C₁₈ column with a mobile phase gradient of water:methanol (95:5, v/v) to methanol, each containing NH₄OAc. This method separately detects and quantifies all three analytes. The 895.5→751.5 m/z transition was used for detection and quantitation of avermectin B_{1a} and 8,9-Z avermectin B_{1a}, and the 881.2→737.0 m/z transition was used for detection and quantitation of avermectin B_{1b}. The validated LOQ for this method is 0.002 ppm for each analyte.

Both of the above methods were adequately validated for data collection in conjunction with the analysis of the field trial samples using control samples fortified with each analyte at the LOQ and at levels similar to those found in the treated crop samples.

860.1380 Storage Stability Data

Adequate storage stability data are available indicating that residues of avermectin B_{1a}, avermectin B_{1b}, and 8,9-Z avermectin B_{1a} are stable under frozen storage for up to 24 months in celery, strawberries, and tomatoes; 29 months in oranges, lemons, and grapefruit; and 35 months in pears (DP#203373, G. J. Herndon, 3/29/95).

In the submitted field trials, all crop samples were stored at -20°C for 1-7 months prior to analysis. These storage conditions and durations are adequately supported by the existing storage stability data.

860.1500 Crop Field Trials

47702803.der (pome fruits) 47702804.der (cucurbit vegetables) 47702805.der (leafy vegetables)
47702806.der (fruiting vegetables) 47702807.der (citrus fruits)

Adequate residue data are available supporting the registered foliar application uses of abamectin formulated as a 0.15 lb ai/gal EC on a wide variety of crops. To support foliar application uses for the proposed SC formulations of abamectin on the same crops and at the same use rates as on the EC label, Syngenta has conducted full scale field trials on the representative crops for the following crop groups: leafy vegetables, cucurbit vegetables, fruiting vegetables, citrus fruits and pome fruits. Based on the results from these field trials, Syngenta is proposing that the residues resulting from foliar applications of the EC formulation are similar to the residues from the SC formulations provided that an adjuvant is included in the spray mix for the SC formulation and the PHI is ≥ 7 days. The results from the field trials using the SC formulation are presented in Table 4 and discussed below.

Table 4. Summary of Residue Data from Crop Field Trials with Abamectin (0.7 lb ai/gal SC).									
Crop/matrix	Total Applic. Rate (lb ai/A)	PHI (days)	Total Abamectin Residues (ppm) ¹						
			n	Min.	Max.	HAFT ²	Median	Mean	Std. Dev.
Leafy vegetables (proposed use = 0.056 lb ai/A total application rate, 7-day PHI)									
Head lettuce, w/ wrapper leaves	0.055-0.058	7	12	<0.004	0.011	0.008	0.004	0.006	0.002
Head lettuce, w/o wrapper leaves		7	12	<0.004	<0.004	0.004	0.004	0.004	N/A
Leaf Lettuce	0.055-0.058	7	12	0.007	0.042	0.032	0.022	0.018	0.011
Spinach	0.057-0.059	7	10	<0.004	0.062	0.054	0.017	0.020	0.020
Celery	0.057-0.059	7	12	0.005	0.022	0.017	0.009	0.009	0.005
Fruiting Vegetables (proposed use = 0.056 lb ai/A total application rate, 7-day PHI)									
Tomato	0.055-0.058	7	22	<0.004	0.007	0.006	0.004	0.004	0.001
Bell peppers	0.057-0.059	7	10	<0.004	0.011	0.010	0.004	0.005	0.003
Chili peppers	0.055-0.059	7	6	<0.004	0.010	0.008	0.006	0.006	0.002
Cucurbit Vegetables (proposed use = 0.056 lb ai/A total application rate, 7-day PHI)									
Cantaloupe	0.057-0.059	7	12	<0.004	<0.004	0.004	0.004	0.004	NA

Table 4. Summary of Residue Data from Crop Field Trials with Abamectin (0.7 lb ai/gal SC).									
Crop/matrix	Total Applic. Rate (lb ai/A)	PHI (days)	Total Abamectin Residues (ppm) ¹						
			n	Min.	Max.	HAFT ²	Median	Mean	Std. Dev.
Cucumber	0.057-0.058	7	12	<0.004	<0.004	0.004	0.004	0.004	NA
Summer Squash	0.057-0.058	7	6	<0.004	<0.004	0.004	0.004	0.004	NA
Citrus Fruits (proposed use = 0.047 lb ai/A total application rate, 7-day PHI) ³									
Oranges	0.046-0.049	7	24	<0.004	0.006	0.005	0.004	0.004	<0.001
Lemons	0.046-0.047	7	10	<0.004	0.008	0.007	0.004	0.005	0.002
Grapefruits	0.046-0.048	7	12	<0.004	<0.004	0.004	0.004	0.004	NA
Pome Fruits (proposed use = 0.047 lb ai/A total application rate, 28-day PHI) ³									
Apple	0.046-0.047	28	24	<0.004	0.008	0.007	0.004	0.005	0.001
Pear	0.044-0.047	28	12	<0.004	0.011	0.009	0.004	0.005	0.002

¹ The combined abamectin residues include avermectin B_{1a}, the 8,9-Z isomer of B_{1a}, and avermectin B_{1b}. The LOQ is 0.002 ppm for B_{1a} (B_{1a} + 8,9-Z isomer) and B_{1b}.

² HAFT = Highest Average Field Trial.

³ The citrus and pome fruit field trials included both dilute and concentrated applications, but there was no difference in residue levels between the two types of applications.

Leafy Vegetables. During the 2008 growing season, six head lettuce, six leaf lettuce, five spinach, and six celery field trials were conducted in Zones 2, 3, 5, 6, 9 and 10 using the 0.7 lb ai/gal SC formulation of abamectin. In each test, abamectin (0.7 lb ai/gal SC) was applied to leafy vegetables as three broadcast foliar applications at rates of 0.017-0.020 lb ai/A and RTIs of 6-8 days, for a total of 0.055-0.059 lb ai/A/season (1x propose rate). Applications were made during vegetative development, using ground equipment at volumes of 12-50 gal/A, and all applications included the use of a NIS as an adjuvant at 0.1-1.5% v/v.

Single control and duplicate treated samples of leaf lettuce, head lettuce (with and without wrapper leaves), spinach, and celery were harvested from the appropriate tests at 7 DAT. In one celery and one leaf lettuce field trial, single treated samples were also collected at 0, 3 and 10 DAT to assess residue decline. Samples were stored at -20°C for up to 7 months prior to extraction for analysis, an interval which is supported by the available storage stability data.

Samples were analyzed for total abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a} and avermectin B_{1b}) using either the HPLC/FLD method (Method No. M-073.1) or the LC/MS/MS method (Method No. Meth-192, rev. 2). The HPLC/FLD method determines avermectin B_{1a} and 8,9-Z avermectin B_{1a} as a single component, and the LC/MS/MS method determines all three analytes separately. The validated LOQ for both methods is 0.002 ppm for each analyte. Although the LC/MS/MS method determines avermectin B_{1a} and 8,9-Z avermectin B_{1a} separately, residues for these two analytes were reported as the combined B_{1a} residues (B_{1a} + 8,9-Z B_{1a}).

Following three foliar applications of abamectin (SC) totaling 0.055-0.059 lb ai/A (1x rate), combined abamectin residues were <0.004-0.011 ppm in/on head lettuce with wrapper leaves, <0.004 ppm in/on head lettuce without wrapper leaves, 0.007-0.042 ppm in/on leaf lettuce, <0.004-0.062 ppm in/on spinach, and 0.005-0.022 ppm in/on celery. Average combined residues were 0.006 ppm for head lettuce with wrapper leaves, 0.004 ppm for head lettuce without wrapper leaves, 0.018 ppm for leaf lettuce, 0.020 ppm for spinach, and 0.009 ppm for celery. The highest average field trial (HAFT) residues were 0.008 ppm for head lettuce with wrapper

leaves, 0.004 ppm for head lettuce without wrapper leaves, 0.032 ppm for leaf lettuce, 0.054 ppm for spinach, and 0.017 ppm for celery.

In the two residue decline tests, combined abamectin residues decreased at longer post-treatment intervals. For leaf lettuce, combined residues were 0.33 ppm at 0 DAT and declined to 0.022 ppm by 10 DAT. For celery, combined residues were 0.32 ppm at 0 DAT and declined to 0.012 ppm by 10 DAT.

Fruiting Vegetables. During the 2008 growing season, eleven tomato, five bell pepper, and three chili pepper field trials were conducted in Zones 2, 3, 5, 6 and 10 using the 0.7 lb ai/gal SC formulation of abamectin. In each test, abamectin (0.7 lb ai/gal SC) was applied to tomatoes and peppers as three broadcast foliar applications at rates of 0.018-0.020 lb ai/A and RTIs of 6-8 days, for a total of 0.055-0.059 lb ai/A/season (1x proposed rate). Applications were made during the later stages of fruit development, using ground equipment in volumes of 18-50 gal/A, and all applications included the use of a NIS as an adjuvant at 0.1-1.5% v/v.

Single control and duplicate treated samples of tomatoes or peppers were harvested from each test at 7 DAT. In one tomato and one pepper trial, single treated samples were also collected at 0, 3 and 10 DAT to assess residue decline. Samples of tomatoes and peppers were stored at -20°C for up to 5 months prior to extraction for analysis, an interval which is supported by the available storage stability data.

Samples were analyzed for total abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) using the LC/MS/MS method (Morse Labs Method No. Meth-192, rev. 2). The validated LOQ is 0.002 ppm for each analyte. Although the LC/MS/MS method determines avermectin B_{1a} and 8,9-Z avermectin B_{1a} separately, residues for these two analytes were reported as the combined B_{1a} residues (B_{1a} + 8,9-Z B_{1a}).

Following three foliar applications at a 1x rate, residues of avermectin B_{1a} (B_{1a} + 8,9-Z B_{1a}) were <0.002-0.005 ppm in/on tomatoes and <0.002-0.009 ppm in/on bell and chili peppers harvested at 7 DAT, and residues of avermectin B_{1b} were <0.002 ppm in/on all tomato and pepper samples. Total abamectin residues were <0.004-0.007 ppm in/on tomatoes, <0.002-0.011 ppm in/on bell peppers, and <0.004-0.010 ppm in/on chili peppers. Average combined residues were 0.004 ppm for tomatoes, 0.005 ppm for bell peppers, and 0.006 ppm for chili peppers.

Data from both the tomato and pepper decline tests indicated that abamectin residues declined at longer post-treatment intervals. Combined residues were 0.007 ppm in tomatoes and 0.010 ppm in/on peppers at 0 DAT and declined to <0.004 ppm in both crops by 3 DAT.

Cucurbit Vegetables. During the 2008 growing season, six cucumber, six cantaloupe and three summer squash field trials were conducted in Zones 2, 3, 5, 6 and 10 using the 0.7 lb ai/gal SC formulation of abamectin. In each test, abamectin (0.7 lb ai/gal SC) was applied to cucumbers, cantaloupes or summer squash as three broadcast foliar applications at rates of 0.019-0.020 lb ai/A and RTIs of 6-9 days, for a total of 0.057-0.059 lb ai/A/season (1x proposed rate). Applications were made during the later stages of fruit development, using ground equipment in volumes of 10-47 gal/A, and all applications included the use of a NIS as an adjuvant at 0.1-1.5% v/v.

Single control and duplicate treated samples of each cucurbit vegetable were harvested from each test at 7 DAT. In one cantaloupe and one summer squash field trial, single treated samples were also collected at 0, 3 and 10 DAT to assess residue decline. Samples were stored at -20°C for up to 4 months prior to extraction for analysis, an interval which is supported by the available storage stability data.

Samples were analyzed for total abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) using the LC/MS/MS method (Morse Labs Method No. Meth-192, rev. 2). The validated LOQ is 0.002 ppm for each analyte. Although the LC/MS/MS method determines avermectin B_{1a} and 8,9-Z avermectin B_{1a} separately, residues for these two analytes were reported as the combined B_{1a} residues (B_{1a} + 8,9-Z B_{1a}).

Following three foliar applications totaling 0.057-0.059 lb ai/A (1x rate), residues of avermectin B_{1a} (B_{1a} + 8,9-Z B_{1a}) and avermectin B_{1b} were each <0.002 ppm in/on all samples of cucumbers, cantaloupes and summer squash harvested at 7 DAT. Combined abamectin residues were <0.004 ppm in/on all cucurbit vegetables, and the average combined residues were 0.004 ppm.

Data from both the cantaloupe and summer squash decline tests indicated that abamectin residues declined at longer post-treatment intervals. Combined residues were 0.012 ppm in/on cantaloupes and 0.005 ppm in/on summer squash at 0 DAT and declined to <0.004 ppm in both crops by 3 DAT.

Citrus Fruits. During the 2007 growing season, twelve orange and six grapefruit field trials were conducted in Zones 3, 6 and 10, and five lemon field trials were conducted in Zones 3 and 10, using the 0.7 lb ai/gal SC formulation of abamectin. At each site, abamectin (0.7 lb ai/gal SC) was applied to citrus trees as two broadcast foliar applications during the later stages of fruit development at rates of 0.022-0.025 lb ai/A and at RTIs of 28-31 days, for a total of 0.046-0.049 lb ai/A/season (1x rate). All applications were made using ground equipment and included the use of a horticultural oil as an adjuvant at 0.1-1.0% v/v. Low volume applications (10-97 gal/A) were used in 13 of the trials and high volume applications (109-270 gal/A) were used in the remaining 10 trials.

Single control and duplicate treated samples of each citrus fruit were harvested from each test at 7 DAT. In two of the lemon trials, single treated samples were also collected at 0, 3, 5 and 10 DAT to assess residue decline. The citrus fruit samples were stored at -20°C for up to 5 months prior to extraction for analysis, an interval which is supported by the available storage stability data.

Samples were analyzed for total abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) using either the HPLC/FLD method (Method No. M-073.1) or the LC/MS/MS method (Method No. Meth-192, rev. 2). The HPLC/FLD method determines avermectin B_{1a} and 8,9-Z avermectin B_{1a} as a single component, and the LC/MS/MS method determines all three analytes separately. The validated LOQ for both methods is 0.002 ppm for each analyte. Although the LC/MS/MS method determines avermectin B_{1a} and 8,9-Z avermectin B_{1a} separately, residues for these two analytes were reported as the combined B_{1a} residues (B_{1a} + 8,9-Z B_{1a}).

Following two foliar applications of abamectin (SC) at rates totaling 0.047-0.049 lb ai/A (1x rate), total B_{1a} residues (B_{1a} + 8,9-Z B_{1a}) were <0.002-0.004 ppm in/on oranges, <0.002 ppm in/on grapefruits, and <0.002-0.006 ppm in/on lemons harvested at 7 DAT. For samples analyzed using the LC/MS/MS method (6 orange samples, 2 grapefruit samples and 2 lemon samples), residues of 8,9-Z avermectin B_{1a} were <0.002 ppm in each sample. Residues of B_{1b} were also <0.002 ppm in/on all samples of oranges, grapefruits and lemons.

Total abamectin residues in/on citrus fruits harvested at 7 DAT were <0.004-0.006 ppm in/on oranges, <0.004 ppm in/on grapefruits, and <0.004-0.008 ppm in/on lemons. Average total residues were 0.004 ppm for oranges and grapefruits and 0.005 ppm for lemons. The total HFT residues were 0.005 ppm for oranges, 0.004 ppm for grapefruits, and 0.007 ppm for lemons. There was no notable difference in residue values between the dilute and concentrated application volumes.

In both lemon residue decline tests, total abamectin residues declined from 0.009 or 0.012 ppm at 0 DAT to <0.004 ppm by 10 DAT, indicating that abamectin residue decline at longer post-treatment intervals.

Pome Fruits. During the 2007-2008 growing seasons, twelve apple and six pear field trials were conducted in Zones 1, 2, 5, 9, 10, and 11, using the 0.7 lb ai/gal SC formulation of abamectin. At each site, abamectin (0.7 lb ai/gal SC) was applied to apple or pear trees as two broadcast foliar applications during the later stages of fruit development at rates of 0.021-0.024 lb ai/A and at RTIs of 20-23 days, for a total of 0.044-0.047 lb ai/A/season (1x the proposed rate). All applications were made using ground equipment and included the use of a horticultural oil as an adjuvant at 0.25-2.5% v/v. Low volume applications (54-91 gal/A) were used in seven of the apple trials and four of the pear trials, and high volume applications (131-269 gal/A) were used in five of the apple trials and two of the pear trials.

Single control and duplicate treated samples of apples or pears were harvested from each test at 28 DAT. In one apple and one pear trial, single treated samples were also collected at 7, 14, 21 and 35 DAT to assess residue decline. Samples of apples and pears were stored at -20°C for up to 4 months prior to extraction for analysis, an interval which is supported by the available storage stability data.

Samples were analyzed for total abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) using either the HPLC/FLD method (Method No. M-073.1) or the LC/MS/MS method (Method No. Meth-192, rev. 2). The HPLC/FLD method determines B_{1a} and 8,9-Z avermectin B_{1a} as a single component, and the LC/MS/MS method determines all three analytes separately. The validated LOQ for both methods is 0.002 ppm for each analyte. Although the LC/MS/MS method determines avermectin B_{1a} and 8,9-Z avermectin B_{1a} separately, residues for these two analytes were reported as the combined B_{1a} residues (B_{1a} + 8,9-Z B_{1a}).

Following two foliar applications at rates totaling 0.044-0.047 lb ai/A (1x rate), residues of avermectin B_{1a} were <0.002-0.006 ppm in/on 24 samples of apples and <0.002-0.009 ppm in/on 12 samples of pears harvested at 28 DAT. Residues of avermectin B_{1b} were <0.002 ppm in/on all apple and pear samples, and residues of 8,9-Z avermectin B_{1a} were <0.002 ppm in/on the 8

apple and 8 pear samples for which the 8,9-Z isomer was separately quantified. Total abamectin residues were <0.004-0.008 ppm and averaged 0.005 ppm in/on apples, and were <0.004-0.011 ppm and averaged 0.005 ppm in/on pears. There was no notable difference in residue values between the dilute and concentrated application volumes.

In the two residue decline tests, residue decline could not be assessed on apples as total abamectin residues were <0.004-0.006 ppm in/on apples harvested from 7 to 35 DAT. However, for pears, the total abamectin residues declined from 0.012 ppm at 7 DAT to <0.004 ppm by 35 DAT.

Conclusions. The submitted field trials on leafy vegetables, cucurbit vegetables, fruiting vegetables, citrus fruits and pome fruits are adequate. All of the field trials were conducted at 1x the rate for the respective crops on the proposed label for the 0.7 lb ai/gal SC formulation, and all applications included the use of either a horticultural oil or a NIS in accordance with the proposed label directions. The appropriate RAC samples were also collected at the proposed PHIs for each crop.

With regards to the MAI SC formulation containing 0.277 lb/gal of abamectin, the residue data supporting the 0.7 lb ai/gal SC formulation will also support the MAI formulation, as the use rates for abamectin on the MAI label are lower than for the same uses on the 0.7 lb ai/gal SC label.

Residues of abamectin in/on each sample were determined using acceptable methods, and the sample storage conditions and durations are supported by adequate storage stability data. The number and geographic representation of the field trials were also adequate as defined in OPPTS 860.1500 for the following crops: head and leaf lettuce, celery, chili pepper, cantaloupe, cucumber, orange, lemon, grapefruit, apple and pear.

The number and geographic representation of the field trials were not adequate as defined in OPPTS 860.1500 for spinach (5 tests submitted), tomato (11 tests submitted), bell pepper (5 tests submitted) and summer squash (3 tests submitted). For complete representation, one additional test each on tomato, spinach, and summer squash would normally be required from Zone 1 and another bell pepper and summer squash field trial would be required from Zone 2. (The field trial reports indicated that the missing crop field trials were actually conducted; however, the missing trials from Zones 1 and 2 did not meet the protocol requirements and were invalidated because the applications did not include the use of an adjuvant.) However, given the low levels of abamectin residues found in samples from the submitted tomato, bell pepper, spinach and squash field trials and the low variability in the residue data across all the crop field trials, HED concludes that the number and geographic representation of the field trials is adequate for all the crops tested. No additional spinach, tomato, bell pepper or summer squash field trials are required to support the use of the SC formulations.

The available field trial data directly support the proposed uses of the SC formulations on leafy vegetables, fruiting vegetables, cucurbit vegetables, citrus fruits and pome fruits. In addition, because abamectin residues resulting from use of the SC formulation were well below the current tolerances for each of these representative crops, HED will translate the existing residue data from the EC formulation of abamectin to support identical uses for the SC formulation provided

that use directions for the SC formulation always require the use of a non-ionic surfactant or horticultural oil in the spray mix and the PHIs are ≥ 7 days.

The proposed SC labels (Agri-Mek SC Miticide/ Insecticide, EPA Reg. No. 100-RGLR and Agri-Flex™ Miticide/Insecticide, EPA Reg. No. 100-RGLN) must be revised so that the label use directions match the available field trials regarding type and amount of surfactant. Since either a non-ionic surfactant or a horticultural oil was used in the SC field trials, the adjuvant specified in the **Directions for Use** for each crop on the SC labels must be a non-ionic surfactant and/or a horticultural oil. (The general term "surfactant" is not adequate since all types of surfactants were not tested.) Also, the amount (v/v) of the non-ionic surfactant and/or crop oil must be specified in the **Directions for Use** for each crop on the SC labels and must be within the range of the amount (v/v) used in the SC field trials.

860.1520 Processed Food and Feed

47702806.de2 (tomato)

Although not required for registration of the new SC formulations, Syngenta also conducted tomato processing studies in conjunction with the submitted tomato field trials. In two field trials conducted in Zone 10 during 2008, abamectin (0.7 lb ai/gal SC) was applied to two separate plots of tomatoes in each trial as three broadcast foliar applications at rates of 0.019-0.020 lb ai/A or 0.094-0.098 lb ai/A and RTIs of 6-7 days, for a totals of 0.057-0.058 lb ai/A (1x rate) or 0.28-0.29 lb ai/A (5x rate). Applications were made during the later stages of fruit development, using ground equipment in volumes of 30-33 gal/A, and all applications included the use of a NIS at 0.1-1.5% v/v.

Single bulk control and treated samples of tomatoes were harvested from each test at 7 DAT, and shipped on the day of harvest under ambient conditions to the processing facility. Samples of whole fruit were collected and frozen at the processor, and the bulk tomato samples from each test were processed within 6 days of harvest into puree and paste using simulated commercial procedures. Samples of puree and paste were collected and frozen, and all samples were stored at -20°C for up to 6 months prior to analysis, an interval which is supported by the available storage stability data.

Samples of whole tomatoes and each processed fraction were analyzed for total abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) using the LC/MS/MS method (Morse Labs Method No. Meth-192, rev. 2). The validated LOQ is 0.002 ppm for each analyte. Although the LC/MS/MS method determines avermectin B_{1a} and 8,9-Z avermectin B_{1a} separately, residues for these two analytes were reported as the combined B_{1a} residues (B_{1a} + 8,9-Z B_{1a}).

Following three broadcast foliar applications of abamectin (SC) at 1x rates, combined abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) were <0.004 ppm in/on whole tomatoes harvested at 7 DAT from both tests. Residues were also <0.004 ppm in puree and paste from the 1x tests; therefore, processing factors for the 1x tests could not be calculated.

In the two 5x rate tests, combined abamectin residues were 0.019 and 0.007 ppm in/on whole tomatoes. Residues in the associated puree fractions were 0.009 and <0.004 ppm, respectively,

for processing factors of 0.47x and 0.57x (Table 5). Residues in the associated paste fractions were 0.022 and 0.005 ppm, respectively, for processing factors of 1.16x and 0.71x. The average processing factors for tomato were 0.52x for puree and 0.94x for paste. The maximum theoretical concentration factor for tomatoes is 5.5x (paste).

Table 5. Summary of Processing Factors for Abamectin.			
Trial Location; year; ID	RAC	Processed Commodity	Processing Factor
Porterville CA 2008 W32CA078448	Tomato	Puree	0.47x
		Paste	1.16x
Huron, CA 2008 W32CA078450	Tomato	Puree	0.57x
		Paste	0.71x

Conclusions. The submitted tomato processing studies are adequate. An acceptable method was used for quantitation of abamectin residues and the sample storage conditions and durations are supported by adequate storage stability data. Based on the results from the 5x rate trials, the average processing factors for total abamectin residues were 0.52x in puree and 0.94x in paste. These data indicate that abamectin residues do not concentrate in tomato processed fractions; therefore, separate tolerances are not required for tomato paste or puree.

860.1550 Tolerances

Tolerances have been established for the combined residues of avermectin B₁ (a mixture of avermectins containing $\geq 80\%$ avermectin B_{1a} and $\leq 20\%$ avermectin B_{1b}) and its delta-8,9-isomer in/on various plant and livestock commodities at levels ranging from 0.005 ppm to 0.20 ppm (40 CFR §180.449). The current abamectin tolerances on crops for which field trials were conducted using the SC formulation are presented in Table 6.

No new tolerances are being proposed in conjunction with the requested use of the new SC formulations of abamectin. Rather, Syngenta is proposing that current tolerances and residue data for the EC formulation be used to support registration of the same uses for the SC formulations on crops with PHIs ≥ 7 days, provided that the SC formulations are applied with an adjuvant.

For all the crops tested using the SC formulation applied as foliar applications at a 1x rate in conjunction with either a horticultural oil or an NIS, the resulting residues of abamectin at the proposed PHI were all well below the existing abamectin tolerances on the respective commodities (Table 6). Based on these data, HED concludes that the existing residue data for foliar application of the EC formulation will support the equivalent crop uses for the SC formulation provided the SC formulation is applied with a non-ionic surfactant or a horticultural oil and the PHI is ≥ 7 days.

Table 6. Tolerance Summary for Abamectin			
Crop/Crop Group	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Total residues resulting from 1x rate foliar applications of the SC formulation
Apple	0.02	0.02	Apples: <0.004-0.008 ppm
Pear	0.02	0.02	Pears: <0.004-0.011 ppm
Citrus	0.02	0.02	Oranges: <0.004-0.006 ppm Lemons: <0.004-0.008 ppm Grapefruits: <0.004 ppm
Vegetable, cucurbit, group 9	0.005	0.005	Cucumbers: <0.004 ppm Squash: <0.004 ppm Cantaloupes: <0.004 ppm
Vegetable, fruiting, group 8	0.02	0.02	Tomatoes: <0.004-0.007 ppm Peppers: <0.004-0.011 ppm
Vegetable, leafy, except brassica, group 4	0.10	0.10	Leaf lettuce: 0.007-0.042 ppm Head lettuce: <0.004-0.011 ppm Spinach: <0.004-0.062 ppm Celery: 0.005-0.022 ppm

References

DP Number: 203373

Subject: Abamectin (Avermectin B₁) for Use in/on the Cucurbit Crop Group (Cucumbers, Melons and Squash). Evaluation of Analytical Methodology and Residue Data.

From: G. Herndon

To: G. LaRocca, L. Arrington and J. Smith

Dated: 3/29/95

MRIDs: 43203801 and 43228601

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Date: 1/21/10

Approved by

Leung Cheng
Leung Cheng, Senior Chemist, RAB III/HED (7509P)

Date: 1/21/10

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B, Durham, NC 27713; submitted 9/30/2009). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47702803. Hamilton, L. (2008) Abamectin - Magnitude of the Residues in or on Apples and Pears as Representative Commodities of Fruit, Pome, Group 11, Final Report: Project Number: T005595/07, T005595, ML08/1423/SYN Unpublished study prepared by Syngenta Crop Protection, Inc. 264 pages.

EXECUTIVE SUMMARY:

Syngenta Crop Protection submitted field trial data supporting the use of abamectin, formulated as a 0.7 lb ai/gal suspension concentrate (SC), on apples and pears as representative commodities of the pome fruit crop group 11. Twelve apple and six pear field trials were conducted in Zones 1, 2, 5, 9, 10, and 11 during the 2007 and 2008 growing seasons. At each site, abamectin (0.7 lb ai/gal SC) was applied to apple or pear trees as two broadcast foliar applications during the later stages of fruit development at rates of 0.021-0.024 lb ai/A and at retreatment intervals (RTIs) of 20-23 days, for a total of 0.044-0.047 lb ai/A/season. All applications were made using ground equipment and included the use of a horticultural oil as an adjuvant at 0.25-2.5% v/v. Low volume applications (54-91 gal/A) were used in seven of the apple trials and four of the pear trials, and high volume applications (131-269 gal/A) were used in five of the apple trials and two of the pear trials.

Single control and duplicate treated samples of apples or pears were harvested from each test 28 days after the second application (DAT). In one apple and one pear trial, single treated samples were also collected at 7, 14, 21 and 35 DAT to assess residue decline. Samples of apples and pears were stored at -20°C for up to 4 months prior to extraction for analysis, an interval which is supported by the available storage stability data.

Samples were analyzed for total abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) using either a high performance liquid chromatography/fluorescence detection (HPLC/FLD) method (Method No. M-073.1) or a liquid chromatography/tandem mass spectrometry (LC/MS/MS) method (Method No. Meth-192, rev. 2). For both methods, residues were extracted with acetonitrile:0.1% phosphoric acid (25:75) and cleaned up by partitioning into hexane and elution through a solid phase extraction (SPE) cartridge. For Method No. M-



073.1, the purified residues were derivatized with trifluoroacetic anhydride and analyzed by HPLC/FLD, which determines avermectin B_{1a} and 8,9-Z avermectin B_{1a} as a single component and avermectin B_{1b} separately. For Method Meth-192/rev.2, the purified residues were analyzed directly by LC/MS/MS, with each analyte being detected and quantified separately. The validated limit of quantitation (LOQ) for both methods is 0.002 ppm for each analyte.

Following two foliar applications of abamectin (0.7 lb ai/gal SC) at rates totaling 0.044-0.047 lb ai/A, residues of avermectin B_{1a} were <0.002-0.006 ppm in/on 24 samples of apples and <0.002-0.009 ppm in/on 12 samples of pears harvested at 28 DAT. Residues of avermectin B_{1b} were <0.002 ppm in/on all apple and pear samples, and residues of 8,9-Z avermectin B_{1a} were <0.002 ppm in/on the 8 apple and 8 pear samples for which the 8,9-Z isomer was separately quantified. Total abamectin residues were <0.004-0.008 ppm and averaged 0.005 ppm in/on apples, and were <0.004-0.011 ppm and averaged 0.005 ppm in/on pears. There was no notable difference in residue values between the dilute and concentrated application volumes.

In the two residue decline tests, residue decline could not be assessed on apples as total abamectin residues were <0.004-0.006 ppm in/on apples harvested from 7 to 35 DAT. However, for pears, the total abamectin residues declined from 0.012 ppm at 7 DAT to <0.004 ppm by 35 DAT.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the pome fruit field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP# 364734.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Tolerances have been established for the combined residues of avermectin B₁ [a mixture of avermectins containing ≥80% avermectin B_{1a} (5-*O*-demethyl avermectin A₁) and ≤20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A₁)] and its delta-8,9-isomer. Abamectin is a natural fermentation product of the soil bacterium *Streptomyces avermitilis*. Abamectin is an insecticide/miticide used to control mites, leafminers, and other insects in commercially important crops, as a seed protectant against nematodes, and in veterinary medicine for treatment of internal and external parasites and mites.

To support registrations for new SC formulations containing abamectin, Syngenta has submitted field trial data on pome fruits. The chemical structure and nomenclature of abamectin and the



physicochemical properties of the technical grade of abamectin are presented in Tables A.1 and A.2.

TABLE A.1. Test Compound Nomenclature.

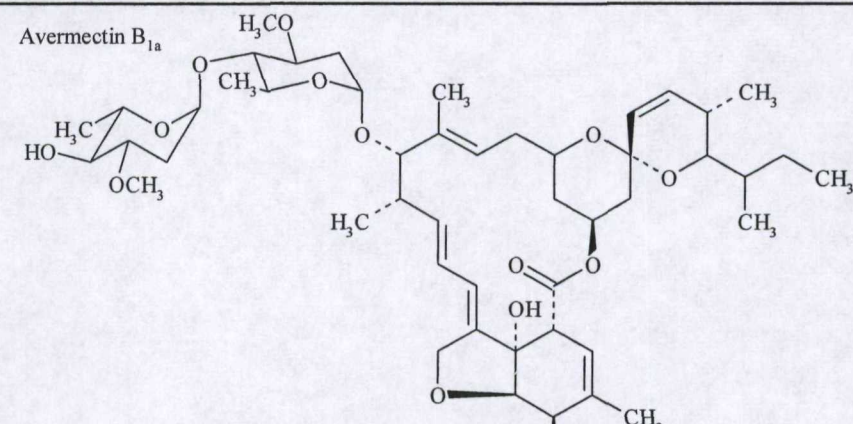
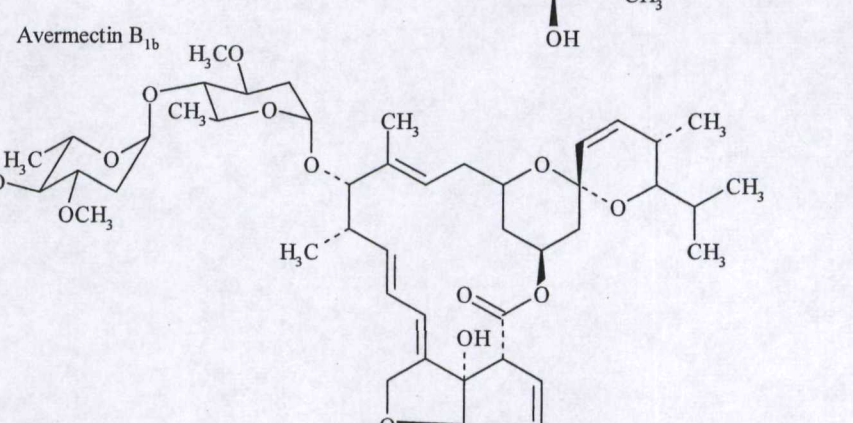
Compound	<div><p>Avermectin B_{1a}</p><p>Avermectin B_{1b}</p></div>
Common name	Abamectin; Avermectin B ₁
Company experimental name	MK-0936
IUPAC name	mixture of (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> ,22 <i>Z</i>)-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i>)-6'-[(<i>S</i>)- <i>sec</i> -butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 ^{4,8} .0 ^{20,24}]-pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-4- <i>O</i> -(2,6-dideoxy-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranosyl)-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranoside and (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> ,22 <i>Z</i>)-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i>)-21,22-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 ^{4,8} .0 ^{20,24}]-pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-4- <i>O</i> -(2,6-dideoxy-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranosyl)-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranoside
CAS name	Avermectin B ₁
CAS registry number	71751-41-2
End-use product (EP)	Agri-Mek SC (0.7 lb ai/gal SC)



TABLE A.2. Physicochemical Properties of the Technical Grade Abamectin.		
Parameter	Value	Reference
Melting point/range	161.8-1.69.4 °C	Study report (MRID 47702803)
pH	8-9 at 25°C	
Density	1.18 x 10 ³ kg/m ³ at 22°C	
Water solubility at 25 °C	1.21 µg/mL at pH 7.57	
Solubility in organic solvents	Acetone 72 g/L	
	Dichloromethane 470 g/L	
	Ethyl acetate 160 g/L	
	Hexane 0.110 g/L	
	Methanol 13 g/L	
	Octanol 83 g/L	
	Toluene 23 g/L	
Vapor pressure at 25 °C	<3.7 x 10 ⁻⁶ Pa	
Dissociation constant (pK _a)	no dissociation constant in aqueous solution	
Octanol/water partition coefficient, Log P	4.4 at pH 7.2	
UV/visible absorption spectrum	Absorbance maxima Neutral : 32,549 l/mol•cm at 245 nm 18,983 l/mol•cm at 255 nm Acidic: 34,515 l/mol•cm at 245 nm 20,977 l/mol•cm at 255 nm Basic: 29,551 l/mol•cm at 245 nm	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

During the 2007-2008 growing seasons, 12 apple field trials were conducted in Zones 1 (3 tests), 2 (1 test), 5 (2 tests), 9 (1 test), 10 (1 test) and 11 (4 tests), and 6 pear field trials were conducted in Zones 1 (1 test), 10 (2 tests), and 11 (3 tests). Trial site conditions are presented in Table B.1.1. The crop varieties grown are identified in Table C. 3.

At each site, a 0.7 lb ai/gal SC formulation of abamectin was applied to apple or pear trees as two broadcast foliar applications at rates of 0.021-0.024 lb ai/A and RTIs of 20-23 days, for a total of 0.044-0.047 lb ai/A/season. Applications were made during late fruit development, using ground equipment. Low application volumes (54-91 gal/A) were used in 7 apples trials and 4 pear trials, and high application volumes (131-269 gal/A) were used in 5 apple trials and 2 pear trials. All applications included the use of a horticultural oil as an adjuvant at 0.25-2.5% v/v. Actual test parameters are reported in Table B.1.2.

The actual temperature recordings and rainfall averages were comparable to average historical values for the study period. Irrigation was used to supplement rainfall as needed. Information on applications of fertilizer and other maintenance pesticides were also provided for each trial site.



TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State; Year)	Soil characteristics			
	Type	% OM	pH	CEC (meq/100g)
Hereford, PA 2007 E04PA078311	Loam	3.1	6.1	11.0
Hereford, PA 2007 E04PA078312	Loam	3.1	6.1	11.0
North Rose, NY 2008 E04NY078313	Loamy Fine Sand	2.8	7.0	10.5
Orefield, PA 2008 E04PA078314	Loam	2.8	5.9	10.7
Crozet, VA 2007 E04VA078315	Sandy Loam	2.9	6.3	4.1
Coopersville, MI 2008 E04MI078316	Sandy Loam	2.4	5.3	5.1
Hart, MI 2008 E04MI078317	Sandy Loam	2.6	6.9	6.7
Cedaredge, CO 2008 E04CO078318	Sandy Loam	4.1	3.8	51.0
Madera, CA 2007 E04CA078319	Sandy Loam	0.74	6.8	7.0
Madera, CA 2007 E04CA078320	Sandy Loam	0.74	6.8	7.0
Ephrata, WA 2007 E04WA078322	Sandy Loam	1.0	7.6	10.8
Ephrata, WA 2007 E04WA078323	Sandy Loam	1.0	7.6	10.8
Hood, River, OR 2007 E04OR078324	Loam	6.9	5.5	7.4
Hood, River OR 2007 E04OR078325	Loam	4.4	6.7	12.4
Ephrata, WA 2007 E04WA078326	Sandy Loam	1.0	7.6	10.8
Hood River, OR 2008 E04OR078327	Sandy Loam	4.9	6.2	8.0
Hood River, OR 2008 E04OR078328	Sandy Loam	4.9	6.2	8.0
Madera, CA 2008 E04CA078329	Sandy Loam	0.74	6.8	7.0



TABLE B.1.2. Study Use Pattern.

Location (City, State; Year) Trial ID	End-Use Product	Application Information						Tank Mix/ Adjuvants
		Method; Timing	TRT # ¹	Volume (gal/A)	Rate (lb ai/A)	RTI ² (days)	Total Rate (lb ai/A)	
Apple Field trials								
Hereford, PA 2007 E04PA078311	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 85	2	82	0.0235	21	0.047	Horticultural oil 0.25% v/v
Hereford, Pa 2007 E04PA078312	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 77 and 79	3	267- 269	0.023	21	0.046	Horticultural oil 0.25% v/v
North Rose, NY 2007 E04PA078313	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 77 and 81	2	65-66	0.023	21	0.046	Horticultural oil 2.5% v/v
Crozet, VA 2007 E04PA078315	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 77 and 79	2	86-87	0.023	21	0.046	Horticultural oil 0.25% v/v
Coopersville, MI 2008 E04PA078316	0.7 lb ai/gal SC	Two broadcast foliar applications with fruit 2.3-2.5”diameter	2	76-78	0.023	21	0.046	Horticultural oil 0.25% v/v
Hart, MI 2008 E04PA078317	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 73 and 81	3	131- 136	0.023	22	0.046	Horticultural oil 2.5% v/v
Cedaredge, CO 2008 E04PA078318	0.7 lb ai/gal SC	Two broadcast foliar applications during fruit development	3	172- 174	0.024, 0.023	21	0.047	Horticultural oil 0.25% v/v
Madera, CA 2007 E04PA078319	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 81 and 88	2	90-91	0.023, 0.024	23	0.047	Horticultural oil 0.75% v/v
Ephrata, WA 2007 E04PA078322	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 82 and 85	2	74-76	0.023	22	0.046	Horticultural oil 0.5% v/v
Ephrata, WA 2007 E04PA078323	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 82 and 85	3	202- 203	0.023	22	0.046	Horticultural oil 0.5% v/v
Hood River, OR 2007 E04PA078324	0.7 lb ai/gal SC	Two broadcast foliar applications , 42 days before harvest and BBCH 81	2	67-72	0.023, 0.024	22	0.047	Horticultural oil 0.5% v/v
Hood River, OR 2007 E04PA078325	0.7 lb ai/gal SC	Two broadcast foliar applications, 35 days before harvest and BBCH 88	3	208- 237	0.023	22	0.046	Horticultural oil 0.5% v/v
Pear Field trials								
Orefield, PA 2008 E04PA078314	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 74 and 77	2	54-56	0.021, 0.023	21	0.044	Horticultural oil 0.25% v/v
Madera, CA 2007 E04PA078320	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 88	2	91	0.024, 0.023	23	0.047	Horticultural oil 0.75% v/v
Ephrata, WA 2007 E04PA078326	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 82 and 85	2	75	0.023	22	0.046	Horticultural oil 0.5% v/v

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**TABLE B.1.2. Study Use Pattern.**

Location (City, State; Year) Trial ID	End-Use Product	Application Information						Tank Mix/ Adjuvants
		Method; Timing	TRT # ¹	Volume (gal/A)	Rate (lb ai/A)	RTI ² (days)	Total Rate (lb ai/A)	
Hood River, OR 2008 E04PA078327	0.7 lb ai/gal SC	Two broadcast foliar applications, 50 days before harvest and BBCH 75	3	148	0.023	22	0.046	Horticultural oil 0.5% v/v
Hood River, OR 2008 E04PA078328	0.7 lb ai/gal SC	Two broadcast foliar applications with fruit at 70% and 90% mature	2	63-64	0.024, 0.023	20	0.047	Horticultural oil 0.5% v/v
Madera, CA 2008 E04PA078329	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 79 and 85	3	201- 202	0.023	21	0.046	Horticultural oil 0.5% v/v

¹ Trt #2 used low volume or concentrated applications (54-91 gal/A) and Trt #3 used high volume or dilute applications (131-269 gal/A).

² RTI = Retreatment Interval

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones	Apple			Pear		
	Submitted	Requested ¹		Submitted	Requested ¹	
		Canada	U.S.		Canada	U.S.
1	3	NA ³	3	1	NA	1
2	1	NA	1	--	NA	--
3	--	NA	--	--	NA	--
4	--	NA	--	--	NA	--
5	2	NA	2	--	NA	--
6	--	NA	--	--	NA	--
7	--	NA	--	--	NA	--
8	--	NA	--	--	NA	--
9	1	NA	1	--	NA	--
10	1	NA	1	2	NA	2
11	4	NA	4	3	NA	3
12	--	NA	--	--	NA	--
13	--	NA	--	--	NA	--
Total	12	NA	12	6	NA	6

¹ Field trials required for a crop group tolerance

² Regions 1A, 5A, 5B, 7A and 14-21 were not included as the proposed use is for the U.S. only.

³ NA = not applicable.

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of apples and pears (≥ 5 lb/sample) were harvested from each trial at 28 DAT. In one apple and one pear trial, single treated samples were also harvested at 7, 14, 21 and 35 DAT to assess residue decline. All samples were frozen at the field sites (time to freezer not reported) and shipped frozen within 1-43 days of harvest, via ACDS freezer truck or on dry ice by overnight courier, to Syngenta (Greensboro, NC). Samples were prepared for analysis by homogenization with dry ice and were stored at -20°C until shipment by



overnight courier on dry ice to the analytical laboratory (Morse Laboratories, Sacramento, CA). Samples were stored at $-20 \pm 5^{\circ}\text{C}$ at the analytical laboratory until analysis.

B.3. Analytical Methodology

Apple and pear samples were analyzed for abamectin residues using either an HPLC/FLD method or an LC/MS/MS method. The HPLC/FLD method (Novartis Method No. M-073.1; "HPLC-Fluorescence Method for the quantitation of Avermectin B₁ and 8,9-Z Avermectin B₁ in/on Fruits and Vegetables") is similar to the current tolerance enforcement method. The LC/MS/MS method (Morse Analytical Method No. Meth-192/revision 2; "Determination of Abamectin Residues in Fruits and Vegetables (Raw Agricultural Commodity) by LC/MS/MS") utilizes the same sample extraction and purification procedures as the HPLC/FLD method, but does not include a derivatization step and uses MS/MS detection for analysis.

For both methods, abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) were extracted with acetonitrile:0.1% phosphoric acid (25:75). Residues were partitioned into hexane, dried over anhydrous Na₂SO₄, and purified by elution through an aminopropyl SPE cartridge with ethyl acetate:methanol (72:25, v/v). Residues were then concentrated to dryness and redissolved in acetonitrile for HPLC/FLD or LC/MS/MS analysis.

For Method M-073.1, the purified residues of all three analytes were derivatized with trifluoroacetic anhydride, and the resulting derivatized residues were analyzed by HPLC/FLD using a reverse phase C₈ column and an isocratic mobile phase of acetonitrile:water (85:15, v/v). For this method, the derivatized residues of avermectin B_{1a} and 8,9-Z avermectin B_{1a} are determined as a single component, and avermectin B_{1b} is determined separately. The validated LOQ for this method is 0.002 ppm for each analyte.

For Method Meth-192/Revision #2, no derivatization step was required. The purified residues were analyzed by LC/MS/MS using a reverse phase C₁₈ column with a mobile phase gradient of water:methanol (95:5, v/v) to methanol, each containing NH₄OAc. This method separately detects and quantifies all three analytes. The 895.5→751.5 m/z transition was used for detection and quantitation of avermectin B_{1a} and 8,9-Z avermectin B_{1a}, and the 881.2→737.0 m/z transition was used for detection and quantitation of avermectin B_{1b}. The validated LOQ for this method is 0.002 ppm for each analyte.

The above methods were validated in conjunction with the analysis of field trial samples. Control samples of pome fruits were fortified with avermectin B_{1a} at 0.002 and 0.033 ppm, avermectin B_{1b} at 0.002 ppm, and 8,9-Z avermectin B_{1a} at 0.002 and 0.033 ppm.

C. RESULTS AND DISCUSSION

The two methods (HPLC/FLD and LC/MS/MS) used for determining residues of avermectin B_{1a}, avermectin B_{1b}, and 8,9-Z avermectin B_{1a} in/on pome fruits were adequately validated in conjunction with the analysis of the field trial samples. The HPLC/FLD method was used to analyze the samples from 8 apple trials and 2 pear trials, and the LC/MS/MS method was used to



analyze samples from 4 apple trials and 4 pear trials. Concurrent method recoveries were within the acceptable range (70-120%) for all fortified samples analyzed using either method (Table C.1). For the HPLC/FLD method (Method No. M-073.1), the average recovery (\pm S.D.) from pome fruits was $94 \pm 4\%$ for avermectin B_{1a} and $81 \pm 6\%$ for avermectin B_{1b}. For the LC/MS/MS method (Method No. Meth-192, Rev. 2), the average recovery (\pm S.D.) from pome fruits was $96 \pm 10\%$ for avermectin B_{1a}, $85 \pm 5\%$ for avermectin B_{1b}, and 80% for 8,9-Z avermectin B_{1a}. Adequate sample chromatograms and example calculations were provided for both methods. Apparent residues of each analyte were <LOQ in/on all untreated samples. Concurrent fortification levels adequately bracketed field trial residue results.

Sample of apples and pears were frozen up to 4 months prior to extraction for analysis (Table C.2). Adequate storage stability data were submitted previously indicating that residues of avermectin B_{1a}, avermectin B_{1b}, and 8,9-Z avermectin B_{1a} are stable under frozen storage for up to 24 months in celery, strawberries, and tomatoes; 29 months in oranges, lemons, and grapefruit; and 35 months in pears (DP# 203373, G. J. Herndon, 3/29/95). These data adequately support the sample storage conditions and durations in the current field trials.

Residues of avermectin B_{1b} were <LOQ (<0.002 ppm) in/on all apple and pear samples (Table C.3), and residues of 8,9-Z avermectin B_{1a} were <LOQ in/on the 8 apple and 8 pear samples for which the 8,9-Z isomer was separately quantified. Only residues of avermectin B_{1a} were quantifiable, at <0.002-0.006 ppm in/on 24 samples of apples and at <0.002-0.009 ppm in/on 12 samples of pears.

Total abamectin residues were <0.004-0.008 ppm and averaged 0.005 ppm in/on apples harvested 28 days after the last of two foliar broadcast applications of abamectin totaling 0.046-0.047 lb ai/A (Table C.4). Total abamectin residues were <0.004-0.011 ppm and averaged 0.005 ppm in/on pears harvested 28 days after the last of two foliar broadcast applications totaling 0.044-0.047 lb ai/A. There was no notable difference in residue values between the dilute and concentrated application volumes.

As total abamectin residues were <0.004-0.006 in/on apples harvested from 7 to 35 DAT, residue decline could not be assessed on apples. However, for pears, the total abamectin residues declined from 0.012 ppm at 7 DAT to <0.004 ppm by 35 DAT, indicating that abamectin residue decline at longer post-treatment intervals.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

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TABLE C.1. Summary of Concurrent Recoveries of Abamectin Residues from Pome Fruits using HPLC/FLD and LC/MS/MS methods.					
Analyte	Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean \pm Std. Dev. (%) ¹
HPLC/FLD Method No. M-073.1					
Avermectin B _{1a}	Apples	0.002	3	93, 86, 95	94 \pm 5
		0.033	3	92, 98, 98	
	Pears	0.002	1	90	93
		0.033	1	96	
	Pome fruit	0.002-0.033	8	86-98	94 \pm 4
Avermectin B _{1b}	Apples	0.002	3	85, 86, 74	82 \pm 7
	Pears	0.002	1	78	NA
	Pome fruit	0.002	4	74-86	81 \pm 6
HLPC/MS/MS Morse Method No. Meth-192					
Avermectin B _{1a}	Apples	0.002	3	85, 98, 90	91 \pm 7
		0.034	3	88, 94, 84	89 \pm 5
	Pears	0.002	3	97, 107, 101	104 \pm 6
		0.034	3	84, 113, 109	102 \pm 16
	Pome fruit	0.002-0.033	12	84-113	96 \pm 10
Avermectin B _{1b}	Apples	0.002	3	77, 81, 86	81 \pm 5
	Pears	0.002	3	89, 90, 87	89 \pm 2
	Pome fruit	0.002	6	77-90	85 \pm 5
8,9-Z Avermectin B _{1a}	Apples	0.002	1	84	80
		0.034	1	76	

¹ Standard deviations were calculated only for fortification levels with ≥ 3 samples.

TABLE C.2. Summary of Storage Conditions.			
Matrix	Storage Temperature (°C)	Actual Storage Duration (months) ¹	Interval of Demonstrated Storage Stability (months) ²
Apples	-20 \pm 5	1-4	35 - pears
Pears			

¹ Interval from harvest to analysis. Extracts were stored 0-3 days prior to analysis.

² Storage stability data are available for pears stored for 35 months (DP# 203373, G. Herndon, 3/29/95).

**TABLE C.3. Residue Data from Pome Fruit Field Trials with Abamectin (SC).**

Trial ID (City, State; Year)	Zone	Crop; Variety	Matrix	TRT# ¹	Total Rate (lb ai/A)	PHI (days)	Abamectin Residues (ppm) ^{2, 3}					
							B _{1a}		B _{1b}		Combined	
Apples												
Hereford, PA 2007 E04PA078311	1	Apple; Law Rome	Fruit	2	0.047	28	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Hereford, PA 2007 E04PA078312	1	Apple; Pink Lady	Fruit	3	0.046	28	0.003	0.002	<0.002	<0.002	0.005	0.004
North Rose, NY 2007 E04PA078313	1	Apple; Ida Red	Fruit	2	0.046	28	0.003	0.006	<0.002	<0.002	0.005	0.008
Crozet, VA 2007 E04PA078315	2	Apple; Fuji	Fruit	2	0.046	28	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Coopersville, MI 2008 E04PA078316	5	Apple; Empire	Fruit	2	0.046	28	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Hart, MI 2008 E04PA078317	5	Apple; Golden Delicious	Fruit	3	0.046	7	<0.002		<0.002		<0.004	
						14	<0.002		<0.002		<0.004	
						21	<0.002		<0.002		<0.004	
						28	<0.002	0.004	<0.002	<0.002	<0.004	0.006
						35	<0.002		<0.002		<0.004	
Cedaredge, CO 2008 E04PA078318	9	Apple; Gala	Fruit	3	0.047	28	0.004	<0.002	<0.002	<0.002	0.006	<0.004
Madera, CA 2007 E04PA078319	10	Apple; Pink lady	Fruit	2	0.047	28	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Ephrata, WA 2007 E04PA078322	11	Apple; Red delicious	Fruit	2	0.046	28	0.003	0.003	<0.002	<0.002	0.005	0.005
Ephrata, WA 2007 E04PA078323	11	Apple; Braeburn	Fruit	3	0.046	28	0.005	0.004	<0.002	<0.002	0.007	0.006
Hood River, OR 2007 E04PA078324	11	Apple; Braeburn	Fruit	2	0.047	28	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Hood River, OR 2007 E04PA078325	11	Apple; Jonagold	Fruit	3	0.046	28	0.002	<0.002	<0.002	<0.002	0.004	<0.004
Pears												
Orefield, PA 2008 E04PA078314	1	Pear; Bartlett	Fruit	2	0.044	28	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Madera, CA 2007 E04PA078320	10	Pear; Huguii	Fruit	2	0.047	28	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Ephrata, WA 2007 E04PA078326	11	Pear; Concord	Fruit	2	0.046	28	0.009	0.005	<0.002	<0.002	0.011	0.007



TABLE C.3. Residue Data from Pome Fruit Field Trials with Abamectin (SC).

Trial ID (City, State; Year)	Zone	Crop; Variety	Matrix	TRT# ¹	Total Rate (lb ai/A)	PHI (days)	Abamectin Residues (ppm) ^{2,3}					
							B _{1a}		B _{1b}		Combined	
Hood River, OR 2008 E04PA078327	11	Pear; Red clap	Fruit	3	0.046	7	0.01		<0.002		0.012	
						14	0.003		<0.002		0.005	
						21	0.004		<0.002		0.006	
						28	0.002	0.002	<0.002	<0.002	0.004	0.004
						35	<0.002		<0.002		<0.004	
Hood River, OR 2008 E04PA078328	11	Pear; Red d'Anjou	Fruit	2	0.047	28	<0.002	0.004	<0.002	<0.002	<0.004	0.006
Madera, CA 2008 E04PA078329	10	Pear; Nojuii	Fruit	3	0.046	28	0.002	<0.002	<0.002	<0.002	0.004	<0.004

¹ Trt #2 used low volume or concentrated applications (54-91 gal/A) and Trt #3 used high volume or dilute applications (131-269 gal/A).

² The LOQ is 0.002 ppm for each analyte. Residue levels determined by the LC/MS/MS method are listed in italics; all other residues were determined using the HPLC/FLD method. Residues of B_{1a} include both B_{1a} and its 8,9-Z isomer.

³ Residues of the 8,9-Z isomer of avermectin B_{1a} were <LOQ in all apple and pear samples analyzed by the LC/MS/MS method.

TABLE C.4. Summary of Residue Data from Pome fruit Field Trials with Abamectin (SC).

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Application volume	Total Abamectin Residues (ppm) ¹						
				n	Min.	Max.	HAFT ²	Median (STMdR)	Mean (STMR)	Std. Dev.
Apple	0.046-0.047	28	Concentrated	14	<0.004	0.008	0.007	0.004	0.005	0.001
			Dilute	10	<0.004	0.007	0.007	0.005	0.005	0.001
			Combined	24	<0.004	0.008	0.007	0.004	0.005	0.001
Pear	0.044-0.047	28	Concentrated	8	<0.004	0.011	0.009	0.004	0.006	0.003
			Dilute	4	<0.004	0.004	0.004	0.004	0.004	N/A
			Combined	12	<0.004	0.011	0.009	0.004	0.005	0.002

¹ Total residues include avermectin B_{1a} (B_{1a} + its 8,9-Z isomer) and avermectin B_{1b}. The LOQ is 0.002 ppm for each analyte for a combined LOQ of 0.004 ppm.

² HAFT = Highest Average Field Trial.

D. CONCLUSION

The submitted apple and pear field trials are adequate. An adequate number of apple and pear field trials were conducted in the appropriate geographical regions. Residues of abamectin were determined using acceptable methods, and the sample storage conditions and durations are supported by adequate storage stability data. The apple and pear field trial data support the use of two broadcast foliar applications of abamectin, formulated as a 0.7 lb ai/gal SC, on pome fruits at up to 0.023 lb ai/A/application, for a total of 0.046 lb ai/A/season. The data also support a minimum RTI of 21 days and a minimum PHI of 28 days for pome fruits. There was no noticeable difference in residue levels between the low and high volume applications, and residues were shown to decline with increasing post-treatment intervals.



E. REFERENCES

DP Number: 203373

Subject: Abamectin (Avermectin B₁) for Use in/on the Cucurbit Crop Group (Cucumbers, Melons and Squash). Evaluation of Analytical Methodology and Residue Data.

From: G. Herndon

To: G. LaRocca, L. Arrington and J. Smith

Dated: 3/29/95

MRID(s): 43203801 and 43228601

F. DOCUMENT TRACKING

RDI: Nancy Dodd (1/21/10); RAB3 ChemTeam (1/21/10); Leung Cheng (1/21/10)

Petition Number: NA

DP#s: 364734 and 364737

PC Code: 122804

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Primary Evaluator Nancy Dodd Date: 1/21/10
Nancy Dodd, Chemist, RAB III/HED (7509P)

Approved by Leung Cheng Date: 1/21/10
Leung Cheng, Senior Chemist, RAB III/HED (7509P)

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B, Durham, NC 27713; submitted 09/30/2009). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47702804. Hamilton, L. (2009) Abamectin - Magnitude of the Residues in or on Cantaloupe, Cucumber and Summer Squash as Representative Commodities of Cucurbits, Group 9 Final Report: Project Number: T005594/07, ML08/1459/SYN. Unpublished study prepared by Syngenta Crop Protection inc. and Morse Laboratories, Inc. 201 pages.

EXECUTIVE SUMMARY:

Syngenta Crop Protection submitted field trial data supporting the use of abamectin, formulated as a 0.7 lb ai/gal suspension concentrate (SC), on cucurbit vegetables. Six cucumber, six cantaloupe, and three summer squash field trials were conducted in Zones 2, 3, 5, 6, and 10 during the 2008 growing season. In each test, a 0.7 lb ai/gal SC formulation of abamectin was applied to cucumbers, cantaloupes or summer squash as three broadcast foliar applications at rates of 0.019-0.020 lb ai/A and retreatment intervals (RTIs) of 6-9 days, for a total of 0.057-0.059 lb ai/A/season. Applications were made during the later stages of fruit development, using ground equipment in volumes of 10-47 gal/A, and all applications included the use of a non-ionic surfactant (NIS) as an adjuvant at 0.1-1.5% v/v.

Single control and duplicate treated samples of each cucurbit vegetable were harvested from each test 7 days after the last application (DAT). In one cantaloupe and one summer squash field trial, single treated samples were also collected at 0, 3 and 10 DAT to assess residue decline. Samples were stored at -20°C for up to 4 months prior to extraction for analysis, an interval which is supported by the available storage stability data.

Samples were analyzed for total abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and abamectin B_{1b}) using a liquid chromatography/tandem mass spectrometry (LC/MS/MS) method (Morse Labs Method No. Meth-192, revision 2). For this method, residues were extracted with acetonitrile:0.1% phosphoric acid (25:75) and cleaned up by partitioning into hexane and elution through a solid phase extraction (SPE) cartridge. The purified residues were then analyzed by LC/MS/MS, with each analyte being detected and quantified separately. The validated limit of quantitation (LOQ) is 0.002 ppm for each analyte. Although the LC/MS/MS method determines avermectin B_{1a} and 8,9-Z avermectin B_{1a} separately, residues for these two analytes were reported as the combined B_{1a} residues (B_{1a} + 8,9-Z B_{1a}).



Residues of avermectin B_{1a} (B_{1a} + 8,9-Z B_{1a}) and avermectin B_{1b} were each <0.002 ppm in/on all samples of cucumbers, cantaloupes and summer squash harvested at 7 DAT. Combined abamectin residues were <0.004 ppm in/on all cucurbit vegetables, and the average combined residues were 0.004 ppm.

Data from both the cantaloupe and summer squash decline tests indicated that abamectin residues declined at longer post-treatment intervals. Combined residues were 0.012 ppm in/on cantaloupes and 0.005 ppm in/on summer squash at 0 DAT and declined to <0.004 ppm in both crops by 3 DAT.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the cucurbit vegetable field trial residue data are classified as scientifically acceptable; however, an insufficient number of summer squash field trials as defined in OPPTS 860.1500 were conducted to support a use on the fruiting vegetables crop group. An additional two summer squash field trials are required from Zones 1 and 2. The study noted that two additional field trials were conducted on summer squash in Zones 1 and 2; however, these two trials were invalidated because the applications did not include the use of an adjuvant. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP# 364734.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Tolerances have been established for the combined residues of avermectin B₁ [a mixture of avermectins containing ≥80% avermectin B_{1a} (5-*O*-demethyl avermectin A₁) and ≤20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A₁)] and its delta-8,9-isomer. Abamectin is a natural fermentation product of the soil bacterium *Streptomyces avermitilis*. Abamectin is an insecticide/miticide used to control mites, leafminers, and other insects in commercially important crops, as a seed protectant against nematodes, and in veterinary medicine for treatment of internal and external parasites and mites.

To support registrations for new SC formulations containing abamectin, Syngenta has submitted field trial data on cucurbit vegetables. The chemical structure and nomenclature of abamectin and the physicochemical properties of the technical grade of abamectin are presented in Tables A.1 and A.2.

**TABLE A.1. Test Compound Nomenclature.**

Compound	<div><p>Avermectin B_{1a}</p></div> <div><p>Avermectin B_{1b}</p></div>
Common name	Abamectin; Avermectin B ₁
Company experimental name	MK-0936
IUPAC name	mixture of (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> ,22 <i>Z</i>)-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i>)-6'-[(<i>S</i>)- <i>sec</i> -butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 ^{4,8} .0 ^{20,24}])pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-4- <i>O</i> -(2,6-dideoxy-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranosyl)-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranoside and (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> ,22 <i>Z</i>)-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i>)-21,22-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 ^{4,8} .0 ^{20,24}])pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-4- <i>O</i> -(2,6-dideoxy-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranosyl)-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranoside
CAS name	Avermectin B ₁
CAS registry number	71751-41-2
End-use product (EP)	Agri-Mek SC (0.7 lb ai/gal SC)



TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound Abamectin.		
Parameter	Value	Reference
Melting point/range	161.8-1.69.4 °C	Study report (MRID 47702804)
pH	8-9 at 25°C	
Density	1.18 x 10 ³ kg/m ³ at 22°C	
Water solubility at 25 °C	1.21 µg/mL at pH 7.57	
Solubility in organic solvents	Acetone 72 g/L Dichloromethane 470 g/L Ethyl acetate 160 g/L Hexane 0.110 g/L Methanol 13 g/L Octanol 83 g/L Toluene 23 g/L	
Vapor pressure at 25 °C	<3.7 x 10 ⁻⁶ Pa	
Dissociation constant (pK _a)	no dissociation constant in aqueous solution	
Octanol/water partition coefficient, Log P	4.4 at pH 7.2	
UV/visible absorption spectrum	Absorbance maxima Neutral : 32,549 l/mol•cm at 245 nm 18,983 l/mol•cm at 255 nm Acidic: 34,515 l/mol•cm at 245 nm 20,977 l/mol•cm at 255 nm Basic: 29,551 l/mol•cm at 245 nm	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Field trial data were submitted from six cucumber tests, six cantaloupe tests, and three summer squash tests conducted during the 2008 growing season. The cucumber field trials were conducted in Zones 2, 3, 5, and 6; the cantaloupe field trials were conducted in Zones 2, 5, 6 and 10; and the summer squash field trials were conducted in Zones 3, 5 and 10. Trial site conditions are presented in Table B.1.1. The crop varieties grown are identified in Table C. 3.

In each test, a 0.7 lb ai/gal SC formulation of abamectin was applied to cucurbit vegetables as three broadcast foliar applications at rates of 0.019-0.020 lb ai/A and RTIs of 6-9 days, for a total of 0.057-0.059 lb ai/A/season. Applications were made during fruit development, using ground equipment in volumes of 10-47 gal/A, and all applications included the use of a NIS as an adjuvant at 0.1-1.5% v/v. Actual test parameters are reported in Table B.1.2.

The study noted that two additional summer squash field trials was conducted in Zones 1 and 2; however, these two trials were invalidated as they did not meet the protocol requirements because the applications did not include the use of an adjuvant.

The actual temperature recordings and rainfall averages were comparable to average historical values for the study period. Irrigation was used to supplement rainfall as needed. Information on applications of fertilizer and other maintenance pesticides were also provided for each trial site.



TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State; Year)	Soil characteristics			
	Type	% OM	pH	CEC (meq/100g)
Athens, GA 2008 E12GA078381	Clay Loam	0.8	6.2	8.0
Suffolk, VA 2008 E07VA078382	Sandy Loam	1.6	5.5	4.2
Chula, GA 2008 E14GA078383	Sand	0.9	7.2	4.2
Bradenton, FL 2008 E16FL078385	Sand	1.9	7.4	9.4
Oviedo, FL 2008 E15FL078386	Sand	0.6	6.9	2.5
Richland, IA 2008 C18IA078387	Silt Loam	3.9	6.655	21.4
Richland, IA 2008 C18IA078388	Silt Loam	3.9	6.655	21.4
Campbell, MN 2008 C11MN078389	Clay Loam	4.1	7.7	22.0
Richland, IA 2008 C18IA078390	Silt Loam	3.9	6.655	21.4
Comanche, OK 2008 C29OK078391	Sandy Clay Loam	1.3	6.7	14.8
Comanche, OK 2008 C29OK078392	Sandy Clay Loam	1.3	6.7	14.8
Madera, CA 2008 W29CA078393	Loamy Sand	0.5	8.2	6.9
Porterville, CA 2008 W32CA078394	Sandy Loam	0.8	8.5	9.1
Madera, CA 2008 W29CA078395	Sandy Loam	1.1	7.7	9.6
Portersville, CA 2008 W32CA078396	Sandy Loam	0.8	8.5	9.1

TABLE B.1.2. Study Use Pattern.

Location (City, State; Year) Trial ID	End-Use Product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (gal/A)	Rate (lb ai/A)	RTI ¹ (days)	Total Rate (lb ai/A)	
Cucumber Field Trials							
Suffolk, VA 2008 E07VA078382	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 65-75	13	0.019-0.020	7	0.058	NIS 0.5% v/v
Chula, GA 2008 E14GA078383	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 51 to medium size fruit	29-30	0.019	7	0.057	NIS 0.25% v/v
Bradenton, FL 2008 E16FL078385	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 61-71	45-47	0.019	7	0.057	NIS 0.25% v/v



TABLE B.1.2. Study Use Pattern.							
Location (City, State; Year) Trial ID	End-Use Product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (gal/A)	Rate (lb ai/A)	RTI ¹ (days)	Total Rate (lb ai/A)	
Richland, IA 2008 C18IA078388	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 63-82	17-21	0.019	7-9	0.057	NIS 0.25% v/v
Campbell, MN 2008 C11MN078389	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 61-82	20	0.019	6-7	0.057	NIS 1.5% v/v
Comanche, OK 2008 C29OK078392	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 70-77	10-11	0.019-0.020	7	0.058	NIS 1.0 % v/v
Cantaloupe Field Trials							
Athens, GA 2008 E12GA078381	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 75-82	28-35	0.019	7	0.057	NIS 0.25% v/v
Richland, IA 2008 C18IA078387	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 70-80	17-30	0.019-0.020	6-8	0.059	NIS 0.1% v/v
Comanche, OK 2008 C29OK078391	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 69-77	10-11	0.019-0.020	7	0.058	NIS 1.0% v/v
Madera, CA 2008 W29CA078393	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 77 and 81	30	0.019	7	0.057	NIS 0.5% v/v
Porterville, CA 2008 W32CA078394	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 81-85	30-32	0.019	7	0.057	NIS 0.5% v/v
Madera, CA 2008 W29CA078395	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 73-81	30	0.019	7	0.058	NIS 0.25% v/v
Summer Squash Field Trials							
Oviedo, FL 2008 E15FL078386	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 62-85	30	0.019	7	0.057	NIS 0.25% v/v
Richland, IA 2008 C18IA078390	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 62-82	17-21	0.019	7-9	0.058	NIS 0.25% v/v
Portersville, CA 2008 W32CA078396	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 45-89	31-32	0.019	7	0.058	NIS 0.50% v/v

¹ RTI = Retreatment Interval

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TABLE B.1.3. Trial Numbers and Geographical Locations.									
NAFTA Growing Zones ²	Cantaloupe			Cucumber			Summer Squash		
	Submitted	Requested ¹		Submitted	Requested ¹		Submitted	Requested ¹	
		Canada	U.S.		Canada	U.S.		Canada	U.S.
1	--	NA	--	--	NA	--	--	NA	1
2	1	NA	1	2	NA	2	--	NA	1
3	--	NA	--	1	NA	1	1	NA	1
4	--	NA	--	--	NA	--	--	NA	--
5	1	NA	1	2	NA	2	1	NA	1
6	1	NA	1	1	NA	1	--	NA	--
7	--	NA	--	--	NA	--	--	NA	--
8	--	NA	--	--	NA	--	--	NA	--
9	--	NA	--	--	NA	--	--	NA	--
10	3	NA	3	--	NA	--	1	NA	1
11	--	NA	--	--	NA	--	--	NA	--
12	--	NA	--	--	NA	--	--	NA	--
13	--	NA	--	--	NA	--	--	NA	--
Total	6	NA	6	6	NA	6	3	NA	5

¹ Field trials required for a crop group tolerance

² Regions 1A, 5A, 5B, 7A and 14-21 were not included as the proposed use is for the U.S. only.

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of cucumbers, cantaloupes or summer squash (24 fruits from 12 plants) were harvested from each site at 7 DAT. At two sites, single treated samples of cantaloupes or summer squash were also harvested at 0, 3 and 10 DAT to assess residue decline. Samples were frozen at the field sites (time to freezer not reported) and shipped frozen within 2-37 days of harvest, via ACDS freezer truck or on dry ice by overnight courier, to Syngenta (Greensboro, NC). At Syngenta, the samples were prepared for analysis by homogenization with dry ice and were then stored at -20°C until shipment by overnight courier on dry ice to the analytical laboratory (Morse Laboratories, Sacramento, CA). Samples were stored at -20 ± 5°C at the analytical laboratory until analysis.

B.3. Analytical Methodology

Samples were analyzed for residues of abamectin (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) using an LC/MS/MS method, Morse Analytical Method, Meth-192/revision 2, "Determination of Abamectin Residues in Fruits and Vegetables (Raw Agricultural Commodity) by LC/MS/MS." This method uses extraction and purification procedures similar to the current tolerance enforcement methods, but uses MS/MS analysis rather than fluorescence detection.

Abamectin residues were extracted with acetonitrile:0.1% phosphoric acid (25:75), and the residues were partitioned into hexane and dried over anhydrous Na₂SO₄. Residues were then purified by elution through an aminopropyl SPE cartridge with ethyl acetate:methanol (72:25, v/v). Residues were then concentrated to dryness and redissolved in acetonitrile for LC/MS/MS analysis. The LC system utilized a reverse phase C₁₈ column with a mobile phase gradient of



water:100 mM NH_4OAc in methanol (95:5, v/v) to 5 mM NH_4OAc in methanol. This method separately detects and quantifies all three analytes. The 895.5 \rightarrow 751.5 m/z transition was used for detection and quantitation of avermectin B_{1a} and 8,9-Z avermectin B_{1a} , and the 881.2 \rightarrow 737.0 m/z transition was used for detection and quantitation of avermectin B_{1b} . The validated LOQ for this method is 0.002 ppm for each analyte, and the LOD was not reported. Although the LC/MS/MS method determines avermectin B_{1a} and 8,9-Z avermectin B_{1a} separately, residues for these two analytes were reported as the combined B_{1a} residues ($\text{B}_{1a} + 8,9\text{-Z } \text{B}_{1a}$).

The method was validated in conjunction with the analysis of field trial samples. Control samples of cucumbers were fortified with avermectin B_{1a} at 0.002 and 0.034 ppm, avermectin B_{1b} at 0.002 ppm, and 8,9-Z avermectin B_{1a} at 0.002 and 0.034 ppm. Control samples of cantaloupes and summer squash were fortified with avermectin B_{1a} at 0.002 and 0.034 ppm and avermectin B_{1b} at 0.002 ppm.

C. RESULTS AND DISCUSSION

The LC/MS/MS method used to determine residues of avermectin B_{1a} , avermectin B_{1b} , and 8,9-Z avermectin B_{1a} was adequately validated in conjunction with the analysis of the field trial samples. The overall average recovery (\pm S.D.) of avermectin B_{1a} was $102 \pm 8\%$ from cucumbers, $106 \pm 10\%$ from cantaloupes, and $95 \pm 7\%$ from summer squash; the overall average recovery (\pm S.D.) of avermectin B_{1b} was $90 \pm 7\%$ from cucumbers, $85 \pm 4\%$ from cantaloupes, and 72% from summer squash; and the average recovery of 8,9-Z avermectin B_{1a} was 93% from cucumbers (Table C.1). Adequate sample chromatograms and example calculations were provided. Apparent residues of each analyte were $<\text{LOQ}$ in/on all untreated samples. Concurrent fortifications adequately bracketed field trial residue results.

Sample of peppers and tomatoes were frozen up to 4 months prior to extraction for analysis (Table C.2). Adequate storage stability data have been submitted previously indicating that residues of avermectin B_{1a} , avermectin B_{1b} , and 8,9-Z avermectin B_{1a} are stable under frozen storage for 24 months in celery, strawberries, and tomatoes; 29 months in oranges, lemons, and grapefruit; and 35 months in pears (DP#203373, G. J. Herndon, 3/29/95). These data adequately support the sample storage conditions and durations in the current field trials.

Following three foliar applications of abamectin (SC) totaling 0.057-0.059 lb ai/A, residues of avermectin B_{1a} ($\text{B}_{1a} + \text{its } 8,9\text{-Z isomer}$) were <0.002 ppm in/on all samples of cucumbers, cantaloupes and summer squash harvested at 7 DAT (Table C.3). Residues of avermectin B_{1b} were also <0.002 ppm in/on all cucumber, cantaloupe and summer squash samples. The combined abamectin residues were <0.004 ppm in/on all cucurbits. The average combined residues and highest average field trial (HAFT) residues were 0.004 ppm for each crop (Table C.4).

In the decline tests, combined residues were 0.012 ppm in/on cantaloupe and 0.005 ppm in/on summer squash at 0 DAT. Combined residues then declined to <0.004 ppm by 3 DAT in both crops.



Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Concurrent Recoveries of Abamectin from Cucurbits using LC/MS/MS method.				
Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean \pm Std. Dev. (%)
Avermectin B_{1a}				
Cantaloupe	0.002	3	91, 107, 121	106 \pm 15
	0.034	3	103, 105, 110	106 \pm 4
	Total	6	91-121	106 \pm 10
Cucumber	0.002	3	90, 98, 109	99 \pm 10
	0.034	3	100, 103, 112	105 \pm 6
	Total	6	90-112	102 \pm 8
Summer Squash	0.002	2	89, 91	90
	0.034	2	97, 104	101
	Total	4	89-104	95 \pm 7
Avermectin B_{1b}				
Cantaloupe	0.002	3	81, 86, 88	85 \pm 4
Cucumber	0.002	3	83, 90, 97	90 \pm 7
Summer Squash	0.002	2	67, 77	72
8,9-Z Avermectin B_{1a}				
Cucumber	0.002	1	88	93
	0.034	1	97	

¹ Standard deviations were calculated only for fortification levels with ≥ 3 samples.

TABLE C.2. Summary of Storage Conditions.			
Matrix	Storage Temperature (°C)	Actual Storage Duration (months) ¹	Interval of Demonstrated Storage Stability (months) ²
Cantaloupe	-20 \pm 5	3	24 -tomato
Cucumber		2-4	
Summer Squash		1-4	

¹ Interval from harvest to analysis. Extracts were stored 1-6 days prior to analysis.

² Storage stability data are available for tomatoes stored for 24 months (DP# 203373, G. Herndon, 3/29/95).

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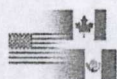


TABLE C.3. Residue Data from Cucurbit Vegetable Field Trials with Abamectin (SC).											
Trial ID (City, State; Year)	Zone	Crop; Variety	Matrix	Total Rate (lb ai/A)	PHI (days)	Abamectin Residues (ppm) ¹					
						B _{1a} ²		B _{1b}		Combined ³	
Cucumber											
Suffolk, VA 2008 E07VA078382	2	Cucumber; Indy F1	Fruit	0.058	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Chula, GA 2008 E14GA078383	2	Cucumber; Daytona	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Bradenton, FL 2008 E16FL078385	3	Cucumber; Speedway	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Richland, IA 2008 C18IA078388	5	Cucumber; Straight 9	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Campbell, MN 2008 C11MN078389	5	Cucumber; Speedway	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Comanche, OK 2008 C29OK078392	6	Cucumber; Poinsett 76	Fruit	0.058	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Cantaloupe											
Athens, GA 2008 E12GA078381	2	Cantaloupe; Improved Rocky Ford	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Richland, IA 2008 C18IA078387	5	Cantaloupe; Delicious 51	Fruit	0.059	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Comanche, OK 2008 C29OK078391	6	Cantaloupe; PMR 45	Fruit	0.058	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Madera, CA 2008 W29CA078393	10	Cantaloupe; Hearts of gold	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Porterville, CA 2008 W32CA078394	10	Cantaloupe; Hale's Best Jumbo	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Madera, CA 2008 W29CA078395	10	Cantaloupe; Hale's Best Jumbo	Fruit	0.058	0	0.010		<0.002		0.012	
					3	0.003		<0.002		0.005	
					7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
					10	<0.002		<0.002		<0.004	

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TABLE C.3. Residue Data from Cucurbit Vegetable Field Trials with Abamectin (SC).											
Trial ID (City, State; Year)	Zone	Crop; Variety	Matrix	Total Rate (lb ai/A)	PHI (days)	Abamectin Residues (ppm) ¹					
						B _{1a} ²		B _{1b}		Combined ³	
Summer Squash											
Oviedo, FL 2008 E15FL078386	3	Summer Squash; Early Summer Crookneck	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Richland, IA 2008 C18IA078390	5	Summer Squash; Summer Crookneck	Fruit	0.058	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Portersville, CA 2008 W32CA078396	10	Summer Squash; Early Summer Yellow Crookneck	Fruit	0.058	0	0.003		<0.002		0.005	
					3	<0.002		<0.002		<0.004	
					7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
					10	<0.002		<0.002		<0.004	

¹ The LOQ is 0.002 ppm for each analyte.

² Although the LC/MS/MS method determines avermectin B_{1a} and 8,9-Z avermectin B_{1a} separately, residues for these two analytes were reported as the combined B_{1a} residues (B_{1a} + 8,9-Z B_{1a}). Residues of the 8,9-Z isomer were <0.002 ppm in all samples.

³ The combined abamectin residues include: avermectin B_{1a}, the 8,9-Z isomer of avermectin B_{1a}, and avermectin B_{1b}.

TABLE C.4. Summary of Residue Data from Cucurbit Field Trials with Abamectin (SC).									
Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm) ¹						
			n	Min.	Max.	HAFT ²	Median (STMdR)	Mean (STMR)	Std. Dev.
Cantaloupe	0.057-0.059	7	12	<0.004	<0.004	0.004	0.004	0.004	NA ³
Cucumber			12	<0.004	<0.004	0.004	0.004	0.004	NA
Summer Squash			6	<0.004	<0.004	0.004	0.004	0.004	NA

¹ The combined abamectin residues include avermectin B_{1a}, the 8,9-Z isomer of avermectin B_{1a}, and avermectin B_{1b}. The LOQ is 0.002 ppm for B_{1a} (B_{1a} + 8,9-Z isomer) and 0.002 ppm for B_{1b}.

² HAFT = Highest Average Field Trial.

³ NA = not applicable.

D. CONCLUSION

The submitted cucurbit vegetable field trials are acceptable. Residues of abamectin were determined using an acceptable method, and the sample storage conditions and durations are supported by adequate storage stability data. However, the geographic representation of the summer squash field trial data is insufficient to support the crop group use. Two additional summer squash field trials are required in Zones 1 and 2. Provided that two more acceptable tests are submitted on summer squash in Zones 1 and 2, the field trial data would support the use of three broadcast foliar applications of abamectin, formulated as a 0.7 lb ai/gal SC, on cucurbit vegetables at up to 0.019 lb ai/A/application, for a total of 0.056 lb ai/A/season. The data also support a minimum RTI of 7 days and a minimum PHI of 7 days.



E. REFERENCES

DP Number: 203373
Subject: Abamectin (Avermectin B₁) for Use in/on the Cucurbit Crop Group (Cucumbers, Melons and Squash). Evaluation of Analytical Methodology and Residue Data.
From: G. Herndon
To: G. LaRocca, L. Arrington and J. Smith
Dated: 3/29/95
MRIDs: 43203801 and 43228601

F. DOCUMENT TRACKING

RDI: Nancy Dodd (1/21/10); RAB3 ChemTeam (1/21/10); Leung Cheng (1/21/10)
Petition Number: NA
DP#s: 364734, 364737
PC Code: 122804

Template Version June 2005

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Primary Evaluator

Nancy Dodd
Nancy Dodd, Chemist, RAB III/HED (7509P)

Date: 1/21/10

Approved by

Leung Cheng
Leung Cheng, Senior Chemist, RAB III/HED (7509P)

Date: 1/21/10

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B, Durham, NC 27713; submitted 09/30/2009). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47702805. Hamilton, L. (2009) Abamectin - Magnitude of the Residues in or on Vegetables, Leafy, Group 4. Final Report: Project Number: T005593/07, ML08/1458/SYN, 192. Unpublished study prepared by Syngenta Crop Protection, Inc. and Morse Laboratories, Inc. 297 pages.

EXECUTIVE SUMMARY:

Syngenta Crop Protection submitted field trial data supporting the use of abamectin, formulated as a 0.7 lb ai/gal suspension concentrate (SC), on leafy vegetables. Six head lettuce, six leaf lettuce, five spinach, and six celery field trials were conducted in Zones 2, 3, 5, 6, 9 and 10 during the 2008 growing season. In each test, a 0.7 lb ai/gal SC formulation of abamectin was applied to leafy vegetables as three broadcast foliar applications at rates of 0.017-0.020 lb ai/A and retreatment intervals (RTIs) of 6-8 days, for a total of 0.055-0.059 lb ai/A/season. Applications were made during vegetative development, using ground equipment at volumes of 12-50 gal/A, and all applications included the use of a non-ionic surfactant (NIS) as an adjuvant at 0.1-1.5% v/v.

Single control and duplicate treated samples of leaf lettuce, head lettuce (with and without wrapper leaves), spinach, and celery were harvested from the appropriate tests 7 days after the last application (DAT). In one celery and one leaf lettuce field trial, single treated samples were also collected at 0, 3 and 10 DAT to assess residue decline. Samples were stored at -20°C for up to 7 months prior to extraction for analysis, an interval which is supported by the available storage stability data.

Samples were analyzed for total abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) using either a high performance liquid chromatography/fluorescence detection (HPLC/FLD) method (Method No. M-073.1) or a liquid chromatography/tandem mass spectrometry (LC/MS/MS) method (Method No. Meth-192, rev. 2). For both methods, residues were extracted with acetonitrile:0.1% phosphoric acid (25:75) and cleaned up by partitioning into hexane and elution through a solid phase extraction (SPE) cartridge. For Method No. M-073.1, the purified residues were derivatized with trifluoroacetic anhydride and analyzed by HPLC/FLD, which determines avermectin B_{1a} and 8,9-Z avermectin B_{1a} as a single component

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and avermectin B_{1b} separately. For Method Meth-192/rev.2, the purified residues were analyzed directly by LC/MS/MS, with each analyte being detected and quantified separately. The validated limit of quantitation (LOQ) for both methods is 0.002 ppm for each analyte.

Following three foliar applications of abamectin (SC) totaling 0.055-0.059 lb ai/A, combined abamectin residues were <0.004-0.011 ppm in/on head lettuce with wrapper leaves, <0.004 ppm in/on head lettuce without wrapper leaves, 0.007-0.042 ppm in/on leaf lettuce, <0.004-0.062 ppm in/on spinach, and 0.005-0.022 ppm in/on celery. Average combined residues were 0.006 ppm for head lettuce with wrapper leaves, 0.004 ppm for head lettuce without wrapper leaves, 0.018 ppm for leaf lettuce, 0.020 ppm for spinach, and 0.009 ppm for celery. The highest average field trial (HAFT) residues were 0.008 ppm for head lettuce with wrapper leaves, 0.004 ppm for head lettuce without wrapper leaves, 0.032 ppm for leaf lettuce, 0.054 ppm for spinach, and 0.017 ppm for celery.

In the two residue decline tests, combined abamectin residues decreased at longer post-treatment intervals. For leaf lettuce, combined residues were 0.33 ppm at 0 DAT and declined to 0.022 ppm by 10 DAT. For celery, combined residues were 0.32 ppm at 0 DAT and declined to 0.012 ppm by 10 DAT.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the leafy vegetable field trial residue data are classified as scientifically acceptable; however, an insufficient number of spinach field trials were conducted to support a use on the leafy vegetables crop group. An additional spinach field trial is required from Zone 1. The study noted that a spinach field trial was conducted in Zone 1; however, this trial was invalidated because the applications did not include the use of an adjuvant. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP# 364734.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

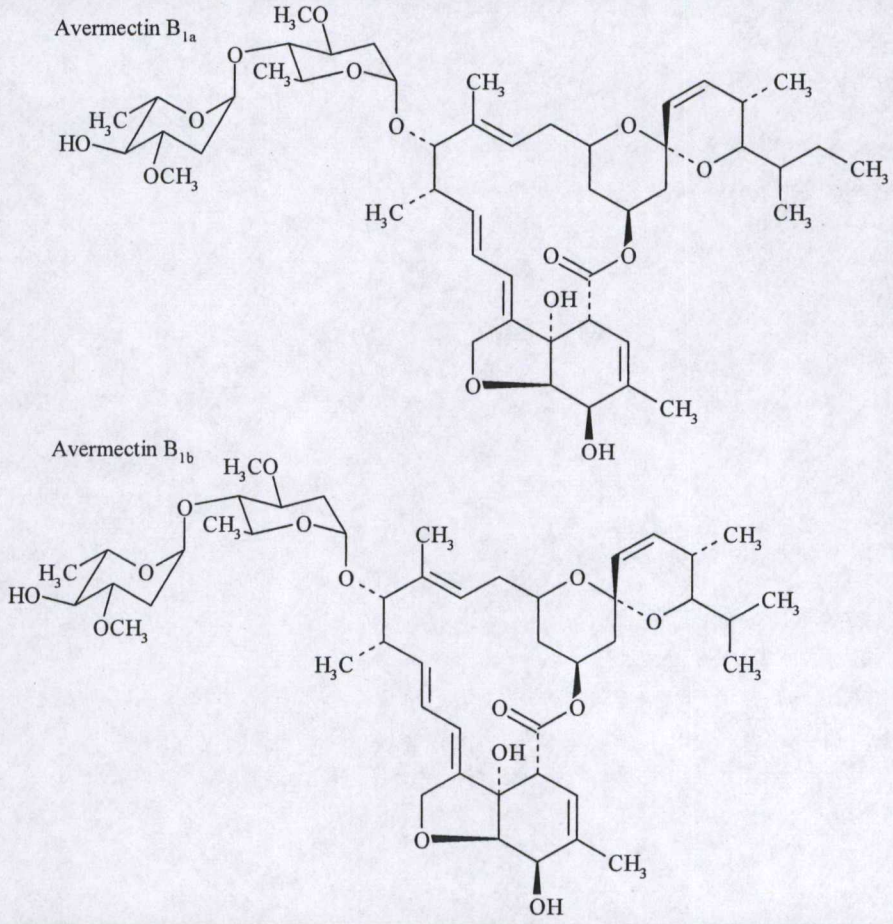
A. BACKGROUND INFORMATION

Tolerances are established for the combined residues of avermectin B₁ [a mixture of avermectins containing ≥80% avermectin B_{1a} (5-*O*-demethyl avermectin A₁) and ≤20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl)avermectin A₁)] and its delta-8,9-isomer. Abamectin is a natural fermentation product of the soil bacterium *Streptomyces avermitilis*. Abamectin is an insecticide/miticide used to control mites, leafminers, and other insects in commercially important crops, as a seed protectant against nematodes, and in veterinary medicine for treatment of internal and external parasites and mites.



To support registrations for new SC formulations containing abamectin, Syngenta has submitted field trial data on leafy vegetables. The chemical structure and nomenclature of abamectin and the physicochemical properties of the technical grade of abamectin are presented in Tables A.1 and A.2.

TABLE A.1. Test Compound Nomenclature.

Compound	
	
Common name	Abamectin; Avermectin B ₁
Company experimental name	MK-0936
IUPAC name	mixture of (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> ,22 <i>Z</i>)-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i>)-6'-[(<i>S</i>)- <i>sec</i> -butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 ^{4,8} .0 ^{20,24}]pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-4- <i>O</i> -(2,6-dideoxy-3- <i>O</i> -methyl-α- <i>L</i> -arabino-hexopyranosyl)-3- <i>O</i> -methyl-α- <i>L</i> -arabino-hexopyranoside and (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> ,22 <i>Z</i>)-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i>)-21,22-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 ^{4,8} .0 ^{20,24}]pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-4- <i>O</i> -(2,6-dideoxy-3- <i>O</i> -methyl-α- <i>L</i> -arabino-hexopyranosyl)-3- <i>O</i> -methyl-α- <i>L</i> -arabino-hexopyranoside
CAS name	Avermectin B ₁
CAS registry number	71751-41-2
End-use product (EP)	Agri-Mek SC (0.7 lb ai/gal SC)

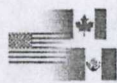


TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound Abamectin.		
Parameter	Value	Reference
Melting point/range	161.8-1.69.4 °C	Study report (MRID 47702805)
pH	8-9 at 25°C	
Density	1.18 x 10 ³ kg/m ³ at 22°C	
Water solubility at 25 °C	1.21 µg/mL at pH 7.57	
Solubility in organic solvents	Acetone 72 g/L Dichloromethane 470 g/L Ethyl acetate 160 g/L Hexane 0.110 g/L Methanol 13 g/L Octanol 83 g/L Toluene 23 g/L	
Vapor pressure at 25 °C	<3.7 x 10 ⁻⁶ Pa	
Dissociation constant (pK _a)	no dissociation constant in aqueous solution	
Octanol/water partition coefficient, Log P	4.4 at pH 7.2	
UV/visible absorption spectrum	Absorbance maxima Neutral : 32,549 l/mol•cm at 245 nm 18,983 l/mol•cm at 255 nm Acidic: 34,515 l/mol•cm at 245 nm 20,977 l/mol•cm at 255 nm Basic: 29,551 l/mol•cm at 245 nm	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Field trial data were submitted from six head lettuce tests, six leaf lettuce tests, five spinach tests, and six celery tests conducted during the 2008 growing season. The head and leaf lettuce field trials were conducted in Zones 2, 3 and 10; the spinach field trials were conducted in Zones 2, 6, 9 and 10; and the celery field trials were conducted in Zones 3, 5 and 10. Trial site conditions are presented in Table B.1.1. The crop varieties grown are identified in Table C. 3.

In each test, a 0.7 lb ai/gal SC formulation of abamectin was applied to the representative leafy vegetables as three broadcast foliar applications at rates of 0.017-0.020 lb ai/A and RTIs of 6-8 days, for a total of 0.055-0.059 lb ai/A/season. Applications were made during vegetative development, using ground equipment in volumes of 12-50 gal/A, and all applications included the use of a NIS as an adjuvant at 0.1-1.5% v/v. Actual test parameters are reported in Table B.1.2.

The study noted that an additional spinach field trial was conducted in Zone 1; however, this trial was invalidated as it did not meet the protocol requirements because the applications did not include the use of an adjuvant.

The actual temperature recordings and rainfall averages were comparable to average historical values for the study period. Irrigation was used to supplement rainfall as needed. Information



on applications of fertilizer and other maintenance pesticides were also provided for each trial site.

TABLE B.1.1. Trial Site Conditions.				
Trial Identification (City, State; Year)	Soil characteristics			
	Type	% OM	pH	CEC (meq/100g)
Elko, SC 2008 E11SC078406	Sand	1.1	6.4	3.6
Suffolk, VA 2008 E07VA078407	Sandy Loam	1.6	5.5	4.2
Suffolk, VA 2008 E07VA078408	Sandy Loam	1.6	5.5	4.2
Belle Glade, FL 2008 E19FL078409	Sandy Loam	58.3	7.2	38.9
Belle Glade, FL 2008 E19FL078410	Sandy Loam	63.9	7.3	35.4
Bradenton, FL 2008 E16FL078411	Sand	1.9	7.4	9.4
Laingsburg, MI 2008 C01MI078412	Sandy Loam	12	6.4	31.8
Madill, OK 2008 W01TX078413	Sandy Loam	1.4	8.0	23.9
Ault, CO 2008 W12CO078414	Loamy Sand	1.8	7.8	29.2
King City, CA 2008 W32CA078415	Clay Loam	1.8	7.9	38.6
Madera, CA 2008 W29CA078416	Sandy Loam	1.1	7.7	9.6
Madera, CA 2008 W29CA078417	Loamy Sand	0.5	8.2	6.9
Santa Maria, CA 2008 W30CA078418	Sandy Loam	0.63	6.9	12.7
Porterville, CA 2008 W32CA078419	Sandy Loam	0.8	8.5	9.1
Guadalupe, CA 2008 W30CA078421	Clay Loam	2.7	7.6	39.6
Corning, CA 2008 W23CA078422	Loam	3.1	6.5	24.7
Fresno, CA 2008 W29CA078423	Sandy Loam	0.7	7.5	16.3
Fresno, CA 2008 W28CA078424	Sandy Loam	0.8	7.6	10.7
King City, CA 2008 W33CA078425	Sandy Loam	0.9	8.1	24.8
Corning, CA 2008 W23BA078426	Loam	3.1	6.5	24.7
Madera, CA 2008 W29CA078427	Loamy Sand	0.2	7.2	5.1
Fresno, CA 2008 W28CA078428	Sandy Loam	0.8	7.6	10.7



TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State; Year)	Soil characteristics			
	Type	% OM	pH	CEC (meq/100g)
Santa Maria, CA 2008 W33CA078429	Sandy Loam	1.0	7.4	12.2

TABLE B.1.2. Study Use Pattern.

TABLE B.1.2. Study Use Pattern.							
Location (City, State; Year) Trial ID	End-Use Product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (gal/A)	Single Rates (lb ai/A)	RTI ¹ (days)	Total Rate (lb ai/A)	
Head Lettuce Trials							
Elko, SC 2008 E11SC078406	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 43 -47	29	0.019	6-7	0.057	NIS 0.25% v/v
Belle Glade, FL 2008 E19FL078410	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 18-45	25-27	0.019	6-7	0.057	NIS 0.25% v/v
Porterville, CA 2008 W32CA078419	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 47-49	30-31	0.017-0.019	6-7	0.055	NIS 0.5% v/v
Guadalupe, CA 2008 W30CA078421	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH BBCH 43-47	29-30	0.019-0.020	7	0.058	NIS 1.0% v/v
Corning, CA 2008 W23BA078422	0.7 lb ai/gal SC	Three broadcast foliar applications at head starting to form to 80% size reached	20	0.018	7-8	0.055	NIS 1.0% v/v
Santa Maria, CA 2008 W30CA078429	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 41-48	24-25	0.019-0.020	7	0.058	NIS 1.0% v/v
Leaf Lettuce Trials							
Suffolk, VA 2008 E07VA078407	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 75-77	12-13	0.019	7	0.058	NIS 0.1% v/v
Belle Glade, FL 2008 E19FL078409	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 18-45	26-28	0.018-0.020	6-7	0.057	NIS 0.25% v/v
Fresno, CA 2008 W28CA078423	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 49	30	0.019	6-8	0.057	NIS 0.1% v/v
Fresno, CA 2008 W28CA078424	0.7 lb ai/gal SC	Three broadcast foliar applications from 20 leaves to mature leaves	30	0.019	7	0.057	NIS 0.5% v/v
King City, CA 2008 W33CA078425	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 31-47	17-24	0.019-0.020	6-8	0.058	NIS 0.1% v/v
Corning, CA 2008 W23BA078426	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 45-49	20	0.018-0.019	7-8	0.055	NIS 1.5% v/v
Spinach Field Trials							
Suffolk, VA 2008 E07VA078408	0.7 lb ai/gal SC	Three broadcast foliar applications. Crop stage not reported	12-13	0.019-0.020	7	0.058	NIS 0.5% v/v
Madill, OK 2008 W01TX078413	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 45-49	29-30	0.019-0.020	7	0.059	NIS 0.5% v/v
Ault, CO 2008 W12CO078414	0.7 lb ai/gal SC	Three broadcast foliar applications during vegetative growth	15-17	0.019-0.020	7	0.058	NIS 0.25% v/v
Madera, CA 2008 W29CA078427	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 49	30-31	0.019-0.020	7	0.058	NIS 0.1% v/v



TABLE B.1.2. Study Use Pattern.

Location (City, State; Year) Trial ID	End-Use Product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (gal/A)	Single Rates (lb ai/A)	RTI ¹ (days)	Total Rate (lb ai/A)	
Fresno, CA 2008 W28CA078428	0.7 lb ai/gal SC	Three broadcast foliar applications from 14-18 leaves	30	0.019	7	0.057	NIS 0.5% v/v
Celery Field Trials							
Bradenton, FL 2008 E16FL078411	0.7 lb ai/gal SC	Three broadcast foliar applications during vegetative growth	49-50	0.019-0.020	7	0.058	NIS 0.1% v/v
Laingsburg, MI 2008 C01MI078412	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 33-49	18	0.019	7-8	0.057	NIS 1.5% v/v
King City, CA 2008 W32CA078415	0.7 lb ai/gal SC ai	Three broadcast foliar applications at BBCH 45-49	31-32	0.019-0.020	6-7	0.059	NIS 0.25% v/v
Madera, CA 2008 W29CA078416	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 45-49	30	0.019	7	0.058	NIS 0.25% v/v
Madera, CA 2008 W29CA078417	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 47-79	30	0.019-0.020	7	0.059	NIS 1.0% v/v
Santa Maria, CA 2008 W30CA078418	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 45-48	28-30	0.018-0.019	7	0.057	NIS 1.0% v/v

¹ RTI = Retreatment Interval

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones ²	Leaf Lettuce			Head Lettuce			Spinach			Celery		
	Submitted	Requested ¹		Submitted	Requested ¹		Submitted	Requested ¹		Submitted	Requested ¹	
		Canada	U.S.		Canada	U.S.		Canada	U.S.		Canada	U.S.
1	--	NA	1 ³	--	NA	1 ³	--	NA	1	--	NA	--
2	1	NA	1 ³	1	NA	1 ³	1	NA	1	--	NA	--
3	1	NA	1	1	NA	1	--	NA	--	1	NA	1
4	--	NA	--	--	NA	--	--	NA	--	--	NA	--
5	--	NA	--	--	NA	--	--	NA	1	1	NA	1
6	--	NA	--	--	NA	--	1	NA	--	--	NA	--
7	--	NA	--	--	NA	--	--	NA	--	--	NA	--
8	--	NA	--	--	NA	--	--	NA	--	--	NA	--
9	--	NA	--	--	NA	--	1	NA	1	--	NA	--
10	4	NA	4	4	NA	4	2	NA	2	4	NA	4
11	--	NA	--	--	NA	--	--	NA	--	--	NA	--
12	--	NA	--	--	NA	--	--	NA	--	--	NA	--
13	--	NA	--	--	NA	--	--	NA	--	--	NA	--
Total	6	NA	6	6	NA	6	5	NA	6	6	NA	6

¹ Field trials required for a crop group tolerance

² Regions 1A, 5A, 5B, 7A and 14-21 were not included as the proposed use is for the U.S. only.

³ Either region 1 or region 2 is required for head and leaf lettuce.

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B.2. Sample Handling and Preparation

Single control and duplicate treated samples of each leafy vegetable (12 plants/sample) were harvested from each site at 7 DAT. Head lettuce was also subsampled to collect heads with and without wrapper leaves. At two sites, single treated samples of celery or leaf lettuce were also harvested at 0, 3 and 10 DAT to assess residue decline. Samples were frozen at the field sites (time to freezer not reported) and shipped frozen within 3-29 days of harvest, via ACDS freezer truck or on dry ice by overnight courier, to Syngenta (Greensboro, NC). At Syngenta, the samples were prepared for analysis by homogenization with dry ice and were then stored at -20°C until shipment by overnight courier on dry ice to the analytical laboratory (Morse Laboratories, Sacramento, CA). Samples were stored at $-20 \pm 5^{\circ}\text{C}$ at the analytical laboratory until analysis.

B.3. Analytical Methodology

Samples were analyzed for abamectin residues using either a HPLC/FLD method or a LC/MS/MS method. The HPLC/FLD method (Novartis Method No. M-073.1; "HPLC-Fluorescence Method for the quantitation of Avermectin B₁ and 8,9-Z Avermectin B₁ in/on Fruits and Vegetables") is similar to the current tolerance enforcement method. The LC/MS/MS method (Morse Analytical Method No. Meth-192/revision 2; "Determination of Abamectin Residues in Fruits and Vegetables (Raw Agricultural Commodity) by LC/MS/MS"), utilizes the same sample extraction and purification procedures as the HPLC/FLD method, but does not include a derivatization step and uses MS/MS detection for analysis.

For both methods, abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) were extracted with acetonitrile:0.1% phosphoric acid (25:75). Residues were partitioned into hexane, dried over anhydrous Na₂SO₄, and purified by elution through an aminopropyl SPE cartridge with ethyl acetate:methanol (72:25, v/v). Residues were then concentrated to dryness and redissolved in acetonitrile for HPLC/FLD or LC/MS/MS analysis.

For Method M-073.1, the purified residues of all three analytes were derivatized with trifluoroacetic anhydride, and the resulting derivatized residues were analyzed by HPLC/FLD using a reverse phase C₈ column and an isocratic mobile phase of acetonitrile:water (85:15, v/v). For this method, the derivatized residues of avermectin B_{1a} and 8,9-Z avermectin B_{1a} are determined as a single component, and avermectin B_{1b} is determined separately. The validated LOQ for this method is 0.002 ppm for each analyte.

For Method Meth-192/Revision #2, no derivatization step was required. The purified residues were analyzed by LC/MS/MS using a reverse phase C₁₈ column with a mobile phase gradient of water:methanol (95:5, v/v) to methanol, each containing NH₄OAc. This method separately detects and quantifies all three analytes. The 895.5→751.5 m/z transition was used for detection and quantitation of avermectin B_{1a} and 8,9-Z avermectin B_{1a}, and the 881.2→737.0 m/z transition was used for detection and quantitation of avermectin B_{1b}. The validated LOQ for this method is 0.002 ppm for each analyte.



The above methods were validated in conjunction with the analysis of field trial samples. Control samples of lettuce, spinach and celery were fortified with avermectin B_{1a} at 0.002-0.50 ppm, avermectin B_{1b} at 0.002 and 0.030 ppm, and 8,9-Z avermectin B_{1a} at 0.002-0.05 ppm.

C. RESULTS AND DISCUSSION

The two methods (HPLC/FLD and LC/MS/MS) used for determining residues of avermectin B_{1a}, avermectin B_{1b}, and 8,9-Z avermectin B_{1a} in/on leafy vegetables were adequately validated in conjunction with the analysis of the field trial samples. The LC/MS/MS method was used to analyze samples from five of the celery field trials, six of the lettuce field trials, and 3 of the spinach field trials. All the other field trials were analyzed using the HPLC/FLD method. With one exception of a 68% recovery of avermectin B_{1a} from celery fortified at 0.002 ppm, the concurrent method recoveries were all within the acceptable range (70-120%) using both methods (Table C.1). For the HPLC/FLD method, the average recovery (\pm S.D.) from leafy vegetables was $88 \pm 9\%$ for avermectin B_{1a}, $77 \pm 5\%$ for avermectin B_{1b}, and $88 \pm 4\%$ for 8,9-Z avermectin B_{1a}. For the LC/MS/MS method, the average recovery (\pm S.D.) from leafy vegetables was $89 \pm 9\%$ for avermectin B_{1a} and $82 \pm 10\%$ for avermectin B_{1b}. Adequate sample chromatograms and example calculations were provided for both methods. Apparent residues of each analyte were <LOQ in/on all untreated samples. Concurrent fortification levels adequately bracketed field trial residue results.

Samples of head and leaf lettuce, spinach and celery were frozen up to 7 months prior to extraction for analysis. Adequate storage stability data have been submitted previously which indicate residues of avermectin B_{1a}, avermectin B_{1b}, and 8,9-Z avermectin B_{1a} are stable under frozen storage for 24 months in celery, strawberries, and tomatoes; 29 months in oranges, lemons, and grapefruit; and 35 months in pears (DP#203373, G. J. Herndon, 3/29/95). These data adequately support the sample storage conditions and durations in the current field trials.

Following three foliar applications of abamectin (SC) totaling 0.055-0.059 lb ai/A, residues of avermectin B_{1a} (B_{1a} + its 8,9-Z isomer) in/on leafy vegetables at 7 DAT were <0.002-0.009 ppm in/on head lettuce with wrapper leaves, <0.002 ppm in/on head lettuce without wrapper leaves, 0.005-0.02 ppm in/on leaf lettuce, <0.002-0.06 ppm in/on spinach, and 0.003-0.02 ppm in/on celery (Table C.3). Residues of avermectin B_{1b} were <0.002 ppm in/on all samples of head lettuce, leaf lettuce and celery and were <0.002-0.004 ppm in/on spinach. Combined abamectin residues were <0.004-0.011 ppm in/on head lettuce with wrapper leaves, <0.004 ppm in/on head lettuce without wrapper leaves, 0.007-0.042 ppm in/on leaf lettuce, <0.004-0.062 ppm in/on spinach, and 0.005-0.022 ppm in/on celery. Average combined residues were 0.006 ppm for head lettuce with wrapper leaves, 0.004 ppm for head lettuce without wrapper leaves, 0.018 ppm for leaf lettuce, 0.020 ppm for spinach, and 0.009 ppm for celery (Table C.4). The HAFT residues were 0.008 ppm for head lettuce with wrapper leaves, 0.004 ppm for head lettuce without wrapper leaves, 0.032 ppm for leaf lettuce, 0.054 ppm for spinach, and 0.017 ppm for celery.

In the two decline tests, combined abamectin residues decreased at longer post-treatment intervals. For leaf lettuce, combined residues were 0.33 ppm at 0 DAT and declined to 0.022



ppm by 10 DAT. For celery, combined residues were 0.32 ppm at 0 DAT and declined to 0.012 ppm by 10 DAT.

TABLE C.1. Summary of Concurrent Recoveries of Abamectin Residues from Leafy Vegetables using HPLC/FLD and LC/MS/MS methods.					
Analyte	Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean \pm Std. Dev. (%) ¹
HPLC/FLD Method No. M-073.1					
Avermectin B _{1a}	Celery	0.002	1	78	85
		0.033	1	92	
	Lettuce	0.002	6	78, 76, 93, 84, 83, 80	88 \pm 10
		0.033	6	88, 98, 97, 88, 76, 94	
		0.50	1	109	
	Spinach	0.002	1	85	89
		0.033	1	92	
	Combined	0.002-0.033	17	76-109	88 \pm 9
Avermectin B _{1b}	Celery	0.002	1	73	73
	Lettuce	0.002	6	73, 76, 80, 77, 72, 72	76 \pm 4
		0.030	1	83	
	Spinach	0.002	1	83	83
	Combined	0.002	9	72-83	77 \pm 5
8,9-Z avermectin B _{1a}	Lettuce	0.002	1	88	90
		0.004	1	92	
	Spinach	0.050	1	85	85
	Combined	0.002-0.033	3	85-92	88 \pm 4
LC/MS/MS Morse Method No. Meth-192					
Avermectin B _{1a}	Celery	0.002	3	68, 90, 97	90 \pm 10
		0.034	3	95, 93, 94	
		0.50	1	96	
	Lettuce	0.002	3	73, 85, 90	89 \pm 9
		0.034	3	97, 94, 92	
	Spinach	0.002	1	74	86 \pm 11
		0.034	1	89	
		0.20	1	95	
	Combined	0.002-0.033	16	68-97	89 \pm 9
Avermectin B _{1b}	Celery	0.002	3	72, 86, 91	81 \pm 9
		0.030	1	74	
	Lettuce	0.002	3	98, 82, 82	87 \pm 9
	Spinach	0.002	1	71	71
	Combined	0.002-0.030	8	71-98	82 \pm 10

¹ Standard deviations were calculated only for fortification levels with ≥ 3 samples.

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TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration (months) ¹	Interval of Demonstrated Storage Stability (months) ²
Celery	-20 ± 5	5	24 – celery
Lettuce		7	
Spinach		6	

¹ Interval from harvest to analysis. Extracts were stored 0-5 days prior to analysis.

² Storage stability data are available for celery stored for 24 months (DP# 203373, G. Herndon, 3/29/95).

TABLE C.3. Residue Data from Leafy Vegetable Field Trials with Abamectin (SC).

TABLE C.3. Residue Data from Leafy Vegetable Field Trials with Abamectin (SC).											
Trial ID (City, State; Year)	Zone	Crop; Variety	Matrix	Total Rate (lb ai/A)	PHI (days)	Abamectin Residues (ppm) ^{1, 2}					
						B _{1a}		B _{1b}		Combined	
Head Lettuce											
Elko, SC 2008 E11SC078406	2	Head Lettuce; Great lakes 118	Head with wrapper leaves	0.058	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
			Head without wrapper leaves		7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Belle Glade, FL 2008 E19FL078410	3	Head Lettuce; Iceburg	Head with wrapper leaves	0.058	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
			Head without wrapper leaves		7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Porterville, CA 2008 W32CA078419	10	Head Lettuce; Cannery Row	Head with wrapper leaves	0.055	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
			Head without wrapper leaves		7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Santa Maria, CA 2008 W30CA078429	10	Head Lettuce; Quest	Head with wrapper leaves	0.058	7	0.009	<0.002	<0.002	<0.002	0.011	<0.004
			Head without wrapper leaves		7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Guadalupe, CA 2008 W30CA078421	10	Head Lettuce; Durrango	Head with wrapper leaves	0.058	7	0.006	0.006	<0.002	<0.002	0.008	0.008
			Head without wrapper leaves		7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Corning, CA 2008 W23BA078422	10	Head Lettuce; Sidewinder	Head with wrapper leaves	0.055	7	0.003	0.006	<0.002	<0.002	0.005	0.008
			Head without wrapper leaves		7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004

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TABLE C.3. Residue Data from Leafy Vegetable Field Trials with Abamectin (SC).											
Trial ID (City, State; Year)	Zone	Crop; Variety	Matrix	Total Rate (lb ai/A)	PHI (days)	Abamectin Residues (ppm) ^{1, 2}					
						B _{1a}		B _{1b}		Combined	
Leaf lettuce											
Suffolk, VA 2008 E07VA078407	2	Leaf Lettuce; Slobolt MTO	Leaves	0.058	7	0.02	0.02	<0.002	<0.002	0.022	0.022
Belle Glade, FL 2008 E19FL078409	3	Leaf Lettuce; Romaine	Leaves	0.057	7	0.006	0.005	<0.002	<0.002	0.008	0.007
Fresno, CA 2008 W28CA078423	10	Leaf Lettuce; Green Leaf Two Star	Leaves	0.057	0	0.31		0.02		0.33	
					3	0.10		0.007		0.107	
					7	0.02	0.02	<0.002	<0.002	0.022	0.022
					10	0.02		<0.002		0.022	
Fresno, CA 2008 W28CA078424	10	Leaf Lettuce; Salad Bowl	Leaves	0.057	7	0.005	0.005	<0.002	<0.002	0.007	0.007
King City, CA 2008 W33CA078425	10	Leaf Lettuce; Sunbelt	Leaves	0.058	7	0.005	0.02	<0.002	<0.002	0.007	0.022
Corning, CA 2008 W23BA078426	10	Leaf Lettuce; Tohema	Leaves	0.055	7	0.04	0.02	<0.002	<0.002	0.042	0.022
Spinach											
Suffolk, VA 2008 E07VA078408	2	Spinach; Tyee F1	Leaves	0.057	7	0.02	0.01	<0.002	<0.002	0.022	0.012
Madill, OK 2008 W01TX078413	6	Spinach; Spargo F1	Leaves	0.058	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Ault, CO 2008 W12CO078414	9	Spinach; Bloomsdale	Leaves	0.059	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Madera, CA 2008 W29CA078427	10	Spinach; Hybrid 7	Leaves	0.058	7	0.06	0.04	0.004	0.003	0.064	0.043
Fresno, CA 2008 W28CA078428	10	Spinach; Bloomsdale	Leaves	0.057	7	0.02	0.02	<0.002	<0.002	0.022	0.022
Celery											
Bradenton, FL 2008 E16FL078411	3	Celery; Golden Pascal	Untrimmed leaf stalk	0.057	7	0.006	0.004	<0.002	<0.002	0.008	0.006
Laingsburg, MI 2008 C01MI078412	5	Celery; Green Bay	Untrimmed leaf stalk	0.059	7	0.003	0.007	<0.002	<0.002	0.005	0.009
King City, CA 2008 W32CA078415	10	Celery; G-15	Untrimmed leaf stalk	0.058	7	0.003	0.003	<0.002	<0.002	0.005	0.005
Madera, CA 2008 W29CA078416	10	Celery; Sayler Sonora	Untrimmed leaf stalk	0.059	7	0.009	0.004	<0.002	<0.002	0.011	0.006
Madera, CA	10	Celery;	Untrimmed	0.059	0	0.31		0.006		0.316	

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**TABLE C.3. Residue Data from Leafy Vegetable Field Trials with Abamectin (SC).**

Trial ID (City, State; Year)	Zone	Crop; Variety	Matrix	Total Rate (lb ai/A)	PHI (days)	Abamectin Residues (ppm) ^{1, 2}					
						B _{1a}		B _{1b}		Combined	
2008 W29CA078417		Sayler Sonora	leaf stalk		3	0.02		<0.002		0.022	
					7	0.02	0.01	<0.002	<0.002	0.022	0.012
					10	0.01		<0.002		0.012	
Santa Maria, CA 2008 W30CA078418	10	Celery; Conquistador	Untrimmed leaf stalk	0.057	7	0.009	0.01	<0.002	<0.002	0.011	0.012

¹ The LOQ is 0.002 ppm for each analyte. Residue levels determined by the LC/MS/MS method are listed in italics; all other residues were determined using the HPLC/FLD method. Residues of B_{1a} include both avermectin B_{1a} and its 8,9-Z isomer.

² Residues of the 8,9-Z isomer of B_{1a} were <LOQ in all samples analyzed by the LC/MS/MS method, with the exception of one spinach sample with 8,9-Z avermectin B_{1a} residues at 0.0025 ppm.

TABLE C.4. Summary of Residue Data from Leafy Vegetable Field Trials with Abamectin (SC).

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Total Abamectin Residues (ppm) ²						
			n	Min.	Max.	HAFT ¹	Median (STMdR)	Mean (STMR)	Std. Dev.
Head with wrapper leaves	0.055-0.058	7	12	<0.004	0.011	0.008	0.004	0.006	0.002
Head without wrapper leaves		7	12	<0.004	<0.004	0.004	0.004	0.004	N/A
Leaf Lettuce	0.055-0.058	7	12	0.007	0.042	0.032	0.022	0.018	0.011
Spinach	0.057-0.059	7	10	<0.004	0.062	0.054	0.017	0.020	0.020
Celery	0.057-0.059	7	12	0.005	0.022	0.017	0.009	0.009	0.005

¹ HAFT = Highest Average Field Trial.

² The LOQ is 0.002 ppm for each analyte.

³ N/A = not applicable.

D. CONCLUSION

The submitted leafy vegetable field trials are acceptable. Residues of abamectin were determined using acceptable methods, and the sample storage conditions and durations are supported by adequate storage stability data. However, the geographic representation of the spinach field trial data is insufficient to support the crop group use. An additional spinach field trial is required in Zone 1. Provided that an acceptable spinach test from Zone 1 is submitted, the field trial data would support the use of three broadcast foliar applications of abamectin, formulated as a 0.7 lb ai/gal SC, on leafy vegetables at up to 0.019 lb ai/A/application, for a total of 0.056 lb ai/A/season. The data also support a minimum RTI of 7 days and a minimum PHI of 7 days.



E. REFERENCES

DP Number: 203373
Subject: Abamectin (Avermectin B₁) for Use in/on the Cucurbit Crop Group (Cucumbers, Melons and Squash). Evaluation of Analytical Methodology and Residue Data.
From: G. Herndon
To: G. LaRocca, L. Arrington and J. Smith
Dated: 3/29/95
MRID(s): 43203801 and 43228601

F. DOCUMENT TRACKING

RD1: Nancy Dodd (1/21/10); ChemTeam (1/21/10); Leung Cheng (1/21/10)
Petition Number: NA
DP#s: 364734 and 364737
PC Code: 122804

Template Version June 2005



Primary Evaluator

Nancy Dodd

Nancy Dodd, Chemist, RAB III/HED (7509P)

Date: 1/21/10

Approved by

Leung Cheng

Leung Cheng, Senior Chemist, RAB III/HED
(7509P)

Date: 1/21/10

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B, Durham, NC 27713; submitted 9/30/2009). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47702806. Hamilton, L. (2009) Abamectin - Magnitude of the Residues in or on Tomatoes and Peppers, including Processing as Representative Commodities of Vegetables, Fruiting, Group 8 Final Report: Project Number: T001871/07. ML08/1460/SYN. Unpublished study prepared by Syngenta Crop Protection, inc. and Morse Laboratories, Inc. 302 pages.

EXECUTIVE SUMMARY:

Syngenta Crop Protection submitted field trial data supporting the use of abamectin, formulated as a 0.7 lb ai/gal suspension concentrate (SC), on fruiting vegetables. Eleven tomato, five bell pepper and three chili pepper field trials were conducted in Zones 2, 3, 5, 6, and 10 during the 2008 growing season. In each test, a 0.7 lb ai/gal SC formulation of abamectin was applied to tomatoes and peppers as three broadcast foliar applications at rates of 0.018-0.020 lb ai/A and retreatment intervals (RTIs) of 6-8 days, for a total of 0.055-0.059 lb ai/A/season. Applications were made during the later stages of fruit development, using ground equipment in volumes of 18-50 gal/A, and all applications included the use of a non-ionic surfactant (NIS) as an adjuvant at 0.1-1.5% v/v.

Single control and duplicate treated samples of tomatoes or peppers were harvested from each test 7 days after the last application (DAT). In one tomato and one pepper trial, single treated samples were also collected at 0, 3 and 10 DAT to assess residue decline. Samples of tomatoes and peppers were stored at -20°C for up to 5 months prior to extraction for analysis, an interval which is supported by the available storage stability data.

Samples were analyzed for total abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) using a liquid chromatography/tandem mass spectrometry (LC/MS/MS) method (Morse Labs Method No. Meth-192, revision 2). For this method, residues were extracted with acetonitrile:0.1% phosphoric acid (25:75) and cleaned up by partitioning into hexane and elution through a solid phase extraction (SPE) cartridge. The purified residues were then analyzed by LC/MS/MS, with each analyte being detected and quantified separately. The validated limit of quantitation (LOQ) is 0.002 ppm for each analyte. Although the LC/MS/MS method determines



avermectin B_{1a} and 8,9-Z avermectin B_{1a} separately, residues for these two analytes were reported as the combined B_{1a} residues (B_{1a} + 8,9-Z B_{1a}).

Residues of avermectin B_{1a} (B_{1a} + 8,9-Z B_{1a}) were <0.002-0.005 ppm in/on tomatoes and <0.002-0.009 ppm in/on bell and chili peppers harvested at 7 DAT, and residues of avermectin B_{1b} were <0.002 ppm in/on all tomato and pepper samples. Combined abamectin residues were <0.004-0.007 ppm in/on tomatoes, <0.002-0.011 ppm in/on bell peppers, and <0.004-0.010 ppm in/on chili peppers. Average combined residues were 0.004 ppm for tomatoes, 0.005 ppm for bell peppers, and 0.006 ppm for chili peppers.

Data from both the tomato and pepper decline tests indicated that abamectin residues declined at longer post-treatment intervals. Combined residues were 0.007 ppm in tomatoes and 0.010 ppm in/on peppers at 0 DAT and declined to <0.004 ppm in both crops by 3 DAT.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the fruiting vegetable field trial residue data are classified as scientifically acceptable; however, an insufficient number of tomato and bell pepper field trials were conducted to support a use on the fruiting vegetables crop group. An additional tomato field trial is required from Zone 1 and another bell pepper field trial is required from Zone 2. The study noted that two additional field trials were conducted, one on tomatoes in Zone 1 and another on bell peppers in Zone 2; however, these two trials were invalidated because the applications did not include the use of an adjuvant. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP# 364734.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

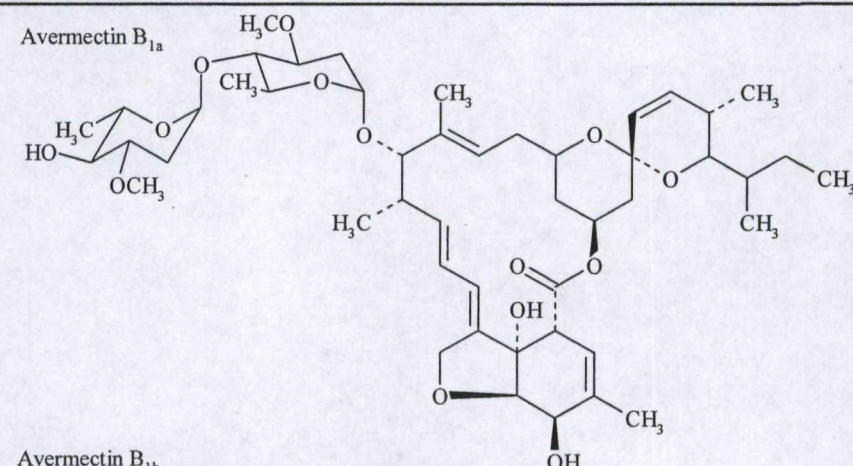
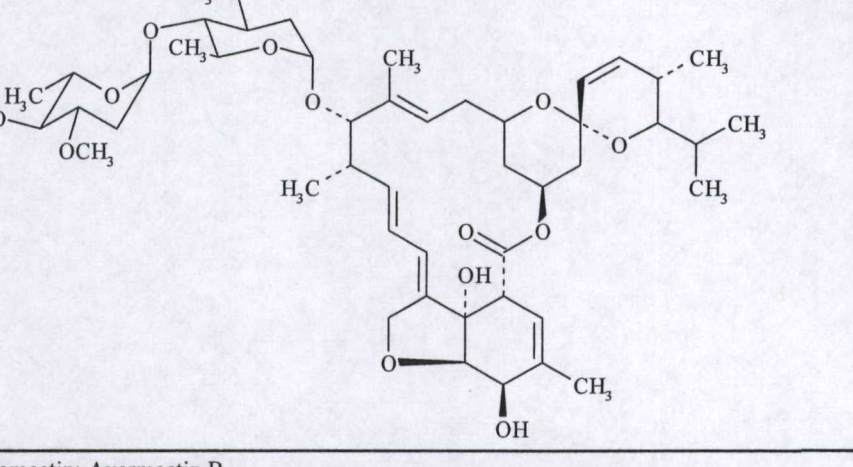
A. BACKGROUND INFORMATION

Tolerances are established for the combined residues of avermectin B₁ [a mixture of avermectins containing ≥80% avermectin B_{1a} (5-*O*-demethyl avermectin A₁) and ≤20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A₁)] and its delta-8,9-isomer. Abamectin is a natural fermentation product of the soil bacterium *Streptomyces avermitilis*. Abamectin is an insecticide/miticide used to control mites, leafminers, and other insects in commercially important crops, as a seed protectant against nematodes, and in veterinary medicine for treatment of internal and external parasites and mites.

To support registrations for new SC formulations containing abamectin, Syngenta has submitted field trial data on fruiting vegetables. The chemical structure and nomenclature of abamectin



and the physicochemical properties of the technical grade of abamectin are presented in Tables A.1 and A.2.

TABLE A.1. Test Compound Nomenclature.	
Compound	<div><p>Avermectin B_{1a}</p><p>Avermectin B_{1b}</p></div>
Common name	Abamectin; Avermectin B ₁
Company experimental name	MK-0936
IUPAC name	mixture of (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> ,22 <i>Z</i>)-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i>)-6'-[(<i>S</i>)- <i>sec</i> -butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 ^{4,8} .0 ^{20,24}])pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-4- <i>O</i> -(2,6-dideoxy-3- <i>O</i> -methyl- α -L-arabino-hexopyranosyl)-3- <i>O</i> -methyl- α -L-arabino-hexopyranoside and (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> ,22 <i>Z</i>)-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i>)-21,22-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 ^{4,8} .0 ^{20,24}])pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-4- <i>O</i> -(2,6-dideoxy-3- <i>O</i> -methyl- α -L-arabino-hexopyranosyl)-3- <i>O</i> -methyl- α -L-arabino-hexopyranoside
CAS name	Avermectin B ₁
CAS registry number	71751-41-2
End-use product (EP)	Agri-Mek SC (0.7 lb ai/gal SC)

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TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound Abamectin.		
Parameter	Value	Reference
Melting point/range	161.8-1.69.4 °C	Study report (MRID 47702806)
pH	8-9 at 25°C	
Density	1.18 x 10 ³ kg/m ³ at 22 °C	
Water solubility at 25 °C	1.21 µg/mL at pH 7.57	
Solubility in organic solvents	Acetone	72 g/L
	Dichloromethane	470 g/L
	Ethyl acetate	160 g/L
	Hexane	0.110 g/L
	Methanol	13 g/L
	Octanol	83 g/L
	Toluene	23 g/L
Vapor pressure at 25 °C	<3.7 x 10 ⁻⁶ Pa	
Dissociation constant (pK _a)	no dissociation constant in aqueous solution	
Octanol/water partition coefficient, Log P	4.4 at pH 7.2	
UV/visible absorption spectrum	Absorbance maxima Neutral : 32,549 l/mol•cm at 245 nm 18,983 l/mol•cm at 255 nm Acidic: 34,515 l/mol•cm at 245 nm 20,977 l/mol•cm at 255 nm Basic: 29,551 l/mol•cm at 245 nm	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Field trial data were submitted from 11 tomato tests (including cherry tomato varieties), 5 bell pepper tests, and 3 chili pepper tests conducted during the 2008 growing season. The tomato field trials were conducted in Zones 2, 3, 5, and 10; the bell pepper field trials were conducted in Zones 3, 5, 6 and 10; and the chili pepper field trials were conducted in Zones 6 and 10. Trial site conditions are presented in Table B.1.1. The crop varieties grown are identified in Table C. 3.

In each test, a 0.7 lb ai/gal SC formulation of abamectin was applied to tomatoes or peppers as three broadcast foliar applications at rates of 0.018-0.020 lb ai/A and RTIs of 6-8 days, for a total of 0.055-0.059 lb ai/A/season. Applications were made during late fruit development, using ground equipment in volumes of 18-50 gal/A, and all applications included the use of a NIS as an adjuvant at 0.1-1.5% v/v. To produce tomato samples for processing, two of the tomato field trials also included a second plot in which the plants received three broadcast foliar applications of abamectin (0.7 lb ai/gal SC) at exaggerated rates of 0.094-0.098 lb ai/A and RTIs of 6-7 days, for a total of 0.28 or 0.29 lb ai/A/season (5x rate). Actual test parameters are reported in Table B.1.2.

The study noted that two additional field trials were conducted on tomatoes in Zone 1 and on bell peppers in Zone 2; however, these two trials were invalidated as they did not meet the protocol requirements because the applications did not include the use of an adjuvant.



The actual temperature recordings and rainfall averages were comparable to average historical values for the study period. Irrigation was used to supplement rainfall as needed. Information on applications of fertilizer and other maintenance pesticides were also provided for each trial site.

TABLE B.1.1. Trial Site Conditions.				
Trial Identification (City, State; Year)	Soil characteristics			
	Type	% OM	pH	CEC (meq/100g)
Athens, GA 2008 E12GA078437	Clay Loam	0.6	6.4	7.6
Quincy, FL 2008 E14FL078438	Sandy Loam	1.6	6.4	11.0
Quincy, FL 2008 E14FL078439	Loamy Sand	1.3	6.4	8.0
Corning, CA 2008 W23CA078440	Loam	3.1	6.5	24.7
Quincy, FL 2008 E14FL078441	Sandy Loam	1.6	6.4	11.0
Richland, IA 2008 C18IA78442	Silt Loam	3.9	6.7	21.4
Richland, IA 2008 C18IA78443	Silt Loam	3.9	6.7	21.4
Madill, OK 2008 W01TX078444	Sandy Loam	1.4	8.0	23.9
Madill, OK 2008 W01TX078445	Fine Sandy Loam	1.4	8.0	23.9
Madera, CA 2008 W29CA078446	Loamy Sand	0.5	8.2	6.9
Porterville, CA 2008 W32CA078447	Clay Loam	1.5	7.7	28.4
Porterville, CA 2008 W32CA078448	Sandy Loam	0.8	8.5	9.1
Madera, CA 2008 W29CA078449	Sandy Loam	1.1	7.7	9.6
Huron, CA 2008 W32CA078450	Clay	1.1	7.8	31.7
Madera, CA 2008 W29CA078451	Loamy Sand	0.5	8.2	6.9
Madera, CA 2008 W29CA078452	Loamy Sand	0.5	8.2	6.9
San Ardo, CA 2008 W32CA078453	Loam	1.5	7.5	38.9
Paso Robles, CA 2008 W33CA078454	Sandy Clay Loam	1.8	7.9	32.7
Corning, CA 2008 W23CA078455	Loam	3.1	6.5	24.7

**TABLE B.1.2. Study Use Pattern.**

Location (City, State; Year) Trial ID	End-Use Product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (gal/A)	Rate (lb ai/A)	RTI ¹ (days)	Total Rate (lb ai/A)	
Tomato Trials							
Athens, GA 2008 E12GA078437	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 75-81	18-30	0.019	7	0.057	NIS 0.25% v/v
Quincy, FL 2008 E14FL078439	0.7 lb ai/gal SC	Three broadcast foliar applications during fruit development	24-25	0.019	7	0.057	NIS 0.25% v/v
Corning, CA 2008 W23CA078440	0.7 lb ai/gal SC	Three broadcast foliar applications during fruit development	20	0.018-0.019	7	0.055	NIS 1.0% v/v
Quincy, FL 2008 E14FL078441	0.7 lb ai/gal SC	Three broadcast foliar applications from flower to red fruit	25-26	0.019	6-8	0.057	NIS 0.25% v/v
Richland, IA 2008 C18IA78442	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 71-81	18-19	0.019	6-8	0.057	NIS 0.25% v/v
Madera, CA 2008 W29CA078446	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 77-81	30-31	0.019	7	0.058	NIS 0.25% v/v
Porterville, CA 2008 W32CA078447	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 72-88	31-33	0.019-0.020	6-8	0.058	NIS 0.5% v/v
Porterville, CA 2008 W32CA078448	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 85-89	30-33	0.019-0.020	6	0.058	NIS 0.1% v/v
				0.095-0.098	6	0.29	
Madera, CA 2008 W29CA078449	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 77-85	30-31	0.019-0.020	7	0.058	NIS 0.25% v/v
Huron, CA 2008 W32CA078450	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 81-89	31-32	0.019	7	0.057	NIS 0.5% v/v
				0.094-0.096	7	0.28	
Madera, CA 2008 W29CA078451	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 75-85	30	0.019	7	0.057	NIS 0.25% v/v
San Ardo, CA 2008 W32CA078453	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 47-88	29-30	0.019	7	0.057	NIS 1.5% v/v



TABLE B.1.2. Study Use Pattern.							
Location (City, State; Year) Trial ID	End-Use Product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (gal/A)	Rate (lb ai/A)	RTI ¹ (days)	Total Rate (lb ai/A)	
Peppers Trials							
Quincy, FL 2008 E14FL078438	0.7 lb ai/gal SC	Three broadcast foliar applications, flowers to mature fruit	19-20	0.019	7	0.057	NIS 0.25% v/v
Richland, IA 2008 C18IA78443	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 73-77	18-20	0.019	7	0.057	NIS 0.25% v/v
Madill, OK 2008 W01TX078444	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 71-76	25-26	0.019-0.020	7	0.059	NIS 0.5% v/v
Madill, OK 2008 W01TX078445	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 73-79	29-30	0.019	7-8	0.057	NIS 0.5% v/v
Madera, CA 2008 W29CA078452	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 73-89	30	0.019	7	0.057	NIS 0.25% v/v
Paso Robles, CA 2008 W33CA078454	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 75-79	31-50	0.019-0.020	7-8	0.058	NIS 0.1% v/v
Corning, CA 2008 W23CA078455	0.7 lb ai/gal SC	Three broadcast foliar applications during fruit development	20	0.018-0.019	7	0.055	NIS 1.0% v/v

¹ RTI = Retreatment Interval.

TABLE B.1.3. Trial Numbers and Geographical Locations.								
NAFTA Growing Zones	Tomatoes			Bell Peppers			Non-Bell Peppers	
	Submitted	Requested ¹		Submitted	Requested ¹		Submitted	Requested ¹
		Canada	U.S.		Canada	U.S.		
1	--	NA	1	--	NA	--		NA
2	1	NA	1	--	NA	1		NA
3	2	NA	2	1	NA	1		NA
4	--	NA	--	--	NA	--		NA
5	1	NA	1	1	NA	1		NA
6	--	NA	--	1	NA	1	1	NA
7	--	NA	--	--	NA	--		NA
8	--	NA	--	--	NA	--		NA
9	--	NA	--	--	NA	--		NA
10	7	NA	7	2	NA	2	2	NA
11	--	NA	--	--	NA	--		NA
12	--	NA	--	--	NA	--		NA
13	--	NA	--	--	NA	--		NA
Total	11	NA	12	5	NA	6	3	NA 3

¹ Field trials required for a crop group tolerance. The requested regions are not specified for non-bell peppers.

² Regions 1A, 5A, 5B, 7A and 14-21 were not included as the proposed use is for the U.S. only.



B.2. Sample Handling and Preparation

Single control and duplicate treated samples of mature peppers and tomatoes (24 fruits from 12 plants) were harvested from each site at 7 DAT. At two sites single treated samples of tomatoes or bell peppers were harvested at 0, 3 and 10 DAT to assess residue decline. Samples were frozen at the field sites (time to freezer not reported) and shipped frozen within 1-36 days of harvest, via ACDS freezer truck or on dry ice by overnight courier, to Syngenta (Greensboro, NC). At Syngenta, the samples were prepared for analysis by homogenization with dry ice and were then stored at -20°C until shipment by overnight courier on dry ice to the analytical laboratory (Morse Laboratories, Sacramento, CA). Samples were stored at $-20 \pm 5^{\circ}\text{C}$ at the analytical laboratory until analysis.

B.3. Analytical Methodology

Samples were analyzed for residues of abamectin (avermectin B_{1a} , 8,9-Z avermectin B_{1a} , and avermectin B_{1b}) using an LC/MS/MS method, Morse Analytical Method, Meth-192/revision 2, "Determination of Abamectin Residues in Fruits and Vegetables (Raw Agricultural Commodity) by LC/MS/MS." This method uses extraction and purification procedures similar to the current tolerance enforcement methods, but uses MS/MS analysis rather than fluorescence detection.

Abamectin residues were extracted with acetonitrile:0.1% phosphoric acid (25:75), and the residues were partitioned into hexane and dried over anhydrous Na_2SO_4 . Residues were then purified by elution through an aminopropyl SPE cartridge with ethyl acetate:methanol (72:25, v/v). Residues in the elute fraction were concentrated to dryness and redissolved in acetonitrile for LC/MS/MS analysis. The LC system utilized a reverse phase C_{18} column with a mobile phase gradient of water:100 mM NH_4OAc in methanol (95:5, v/v) to 5 mM NH_4OAc in methanol. This method separately detects and quantifies all three analytes. The $895.5 \rightarrow 751.5$ m/z transition was used for detection and quantitation of avermectin B_{1a} and 8,9-Z avermectin B_{1a} , and the $881.2 \rightarrow 737.0$ m/z transition was used for detection and quantitation of avermectin B_{1b} . The validated LOQ for this method is 0.002 ppm for each analyte, and the LOD was not reported. Although the method separately detects and quantifies avermectin B_{1a} and its 8,9-Z isomer, the report presented residues of B_{1a} as the combined residues of B_{1a} + its 8,9-Z isomer.

The method was validated in conjunction with the analysis of field trial samples. Control samples of tomatoes were fortified with avermectin B_{1a} at 0.002-0.10 ppm, avermectin B_{1b} at 0.002-0.006 ppm, and 8,9-Z avermectin B_{1a} at 0.002 and 0.033 ppm. Control samples of peppers were fortified with avermectin B_{1a} at 0.002-0.033 ppm and avermectin B_{1b} at 0.002 ppm.

C. RESULTS AND DISCUSSION

The LC/MS/MS method used to determine residues of avermectin B_{1a} , avermectin B_{1b} , and 8,9-Z avermectin B_{1a} was adequately validated in conjunction with the analysis of the field trial samples. The overall average recovery (\pm S.D.) of avermectin B_{1a} was $98 \pm 13\%$ from tomatoes and $98 \pm 7\%$ from peppers; the overall average recovery (\pm S.D.) of avermectin B_{1b} was $91 \pm$



15% from tomatoes and $95 \pm 9\%$ from peppers; and the average recovery of 8,9-Z avermectin B_{1a} was 95% from tomatoes (Table C.1). Adequate sample chromatograms and example calculations were provided. Apparent residues of each analyte were <LOQ in/on all untreated samples. Concurrent fortifications adequately bracketed field trial residue results.

Sample of peppers and tomatoes were frozen up to 5 months prior to extraction for analysis (Table C.2). Adequate storage stability data has been submitted previously indicating that residues of avermectin B_{1a}, avermectin B_{1b}, and 8,9-Z avermectin B_{1a} are stable under frozen storage for 24 months in celery, strawberries, and tomatoes; 29 months in oranges, lemons, and grapefruit; and 35 months in pears (DP#203373, G. J. Herndon, 3/29/95). These data adequately support the sample storage conditions and durations in the current field trials.

Following three foliar applications of abamectin (SC) totaling 0.055-0.059 lb ai/A, residues of avermectin B_{1a} (B_{1a} + its 8,9-Z isomer) were <0.002-0.005 ppm in/on tomatoes and <0.002-0.009 ppm in/on bell and chili peppers harvested at 7 DAT (Table C.3). (Note: Data in the analytical report also indicate that residues of 8,9-Z avermectin B_{1a} were <LOQ in all tomato and pepper samples.) Residues of avermectin B_{1b} were <0.002 ppm in/on all tomato and pepper samples. The combined abamectin residues were <0.004-0.007 ppm in/on tomatoes, <0.002-0.011 ppm in/on bell peppers, and <0.004-0.010 ppm in/on chili peppers. Average combined residues were 0.004 ppm for tomatoes, 0.005 ppm for bell peppers, and 0.006 ppm for chili peppers (Table C.4). Combined highest average field trial (HAFT) residues were 0.006 ppm for tomatoes, 0.010 ppm for bell peppers, and 0.008 ppm for chili peppers

In the tomato decline study, combined residues were 0.007 ppm at 0 DAT and declined to <0.004 ppm by 3 DAT. In the pepper decline study, combined residues were 0.010 ppm at 0 DAT and declined to <0.004 ppm by 3 DAT.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

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TABLE C.1. Summary of Concurrent Recoveries of Abamectin from Fruiting Vegetables using an LC/MS/MS method.				
Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean \pm Std. Dev. (%) ¹
Avermectin B_{1a}				
Pepper	0.002	4	88, 91, 92, 108	95 \pm 9
	0.03	4	95, 96, 103, 106	100 \pm 5
	Total	8	88-108	97 \pm 7
Tomato	0.002	14	75, 81, 82, 86, 96, 98, 101, 102, 109, 109, 110, 114, 117, 119	100 \pm 14
	0.03	11	77, 80, 83, 91, 93, 99, 100, 100, 107, 107, 111	95 \pm 11
	0.05	2	96, 113	105
	0.10	1	100	100
	Total	28	75-119	98 \pm 13
Avermectin B_{1b}				
Pepper	0.002	4	86, 91, 96, 107	95 \pm 9
Tomato	0.002	11	66, 69, 72, 75, 76, 86, 89, 99, 100, 105, 112	86 \pm 16
	0.003	2	97, 114	106
	0.006	1	105	105
	Total	14	66-114	91 \pm 15
8,9-Z avermectin B_{1a}				
Tomato	0.002	1	87	95
	0.03	1	103	

¹ Standard deviations were calculated only for fortification levels with ≥ 3 samples.

TABLE C.2. Summary of Storage Conditions.			
Matrix	Storage Temperature (°C)	Actual Storage Duration (months) ¹	Interval of Demonstrated Storage Stability (months) ²
Tomatoes	-20 \pm 5	2-5	24 - tomatoes
Peppers		3-5	

¹ Interval from harvest to analysis. Extracts were stored 0-9 days prior to analysis.

² Storage stability data are available for tomatoes stored for 24 months (DP# 203373, G. Herndon, 3/29/95).

TABLE C.3. Residue Data from Fruiting Vegetable Field Trials with Abamectin (SC).											
Trial ID (City, State; Year)	Zone	Crop; Variety	Matrix	Total Rate (lb ai/A)	PHI (days)	Abamectin Residues (ppm) ¹					
						B _{1a} ²	B _{1b}		Combined ³		
Tomatoes											
Athens, GA 2008 E12GA078437	2	Tomato; Supersonic	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Quincy, FL 2008 E14FL078439	3	Tomato; Crista	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Corning, CA 2008 W23CA078440	3	Tomato; AB-2	Fruit	0.055	7	0.003	0.005	<0.002	<0.002	0.005	0.007
Quincy, FL 2008 E14FL078441	5	Tomato, Cherry; Camilla	Fruit	0.057	7	0.003	0.003	<0.002	<0.002	0.005	0.005



TABLE C.3. Residue Data from Fruiting Vegetable Field Trials with Abamectin (SC).											
Trial ID (City, State; Year)	Zone	Crop; Variety	Matrix	Total Rate (lb ai/A)	PHI (days)	Abamectin Residues (ppm) ¹					
						B _{1a} ²		B _{1b}		Combined ³	
Richland, IA 2008 C18IA78442	5	Tomato; Bush Celebrity	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Madera, CA 2008 W29CA078446	10	Tomato; 6366	Fruit	0.058	7	0.002	<0.002	<0.002	<0.002	0.004	<0.004
Porterville, CA 2008 W32CA078447	10	Tomato; Shady Lady	Fruit	0.058	0	0.005		<0.002		0.007	
					3	<0.002		<0.002		<0.004	
					7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
					10	<0.002		<0.002		<0.004	
Porterville, CA 2008 W32CA078448	10	Tomato; UC 82-B	Fruit	0.058	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
				0.29	7	0.010	0.013	<0.002	<0.002	0.012	0.015
Madera, CA 2008 W29CA078449	10	Tomato; Shady	Fruit	0.058	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Huron, CA 2008 W32CA078450	10	Tomato; AB-2	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
				0.28	7	0.008	0.009	<0.002	<0.002	0.010	0.011
Madera, CA 2008 W29CA078451	10	Tomato, cherry; Naomi	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Peppers											
Quincy, FL 2008 E14FL078438	3	Pepper, Bell; Aristotle	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Richland, IA 2008 C18IA78443	6	Pepper, Bell; California Wonder	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Madill, OK 2008 W01TX078444	6	Pepper, Bell; Wizard	Fruit	0.059	7	0.009	0.007	<0.002	<0.002	0.011	0.009
Madill, OK 2008 W01TX078445	10	Pepper, Hot; TAM jalapeno	Fruit	0.057	7	0.008	0.004	<0.002	<0.002	0.010	0.006
Madera, CA 2008 W29CA078452	10	Pepper, Bell; Chalice	Fruit	0.057	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
San Ardo, CA 2008 W32CA078453	10	Pepper, Bell; Moody	Fruit	0.057		0.008		<0.002		0.010	
						<0.002		<0.002		<0.004	
					7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
						<0.002		<0.002		<0.004	
Paso Robles, CA 2008 W33CA078454	10	Pepper, Hot; Serrano	Fruit	0.058	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Corning, CA 2008 W23CA078455	10	Pepper; Hot, Pimento	Fruit	0.055	7	0.004	0.003	<0.002	<0.002	0.006	0.005

¹ The LOQ is 0.002 ppm for each analyte.

² Although residue of avermectin B_{1a} and 8,9-Z avermectin B_{1a} were determined separately, the report presented residues of B_{1a} as the combined residues of B_{1a} and its 8,9-Z isomer. Residues of the 8,9-Z isomer were <0.002 ppm in all tomato and pepper samples.

³ The combined abamectin residues include: avermectin B_{1a}, the 8,9-Z isomer of avermectin B_{1a}, and avermectin B_{1b}.

**TABLE C.4. Summary of Residue Data from Fruiting Vegetable Field Trials with Abamectin (SC).**

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm) ¹						
			n	Min.	Max.	HAFT ²	Median (STMdR)	Mean (STMR)	Std. Dev.
Tomato	0.055-0.058	7	22	<0.004	0.007	0.006	0.004	0.004	0.001
Bell Pepper	0.057-0.059	7	10	<0.004	0.011	0.010	0.004	0.005	0.003
Hot Pepper	0.055-0.059	7	6	<0.004	0.010	0.008	0.006	0.006	0.002

¹ The combined abamectin residues include avermectin B_{1a}, the 8,9-Z isomer of avermectin B_{1a}, and avermectin B_{1b}. The LOQ is 0.002 ppm for B_{1a} (B_{1a} + 8,9-Z isomer) and B_{1b}.

² HAFT = Highest Average Field Trial.

D. CONCLUSION

The submitted tomato and pepper field trials are acceptable. Residues of abamectin were determined using an acceptable method, and the sample storage conditions and durations are supported by adequate storage stability data. However, the geographic representations of the tomato and pepper field trials are insufficient to support a crop group use. Another tomato field trial is required in Zone 1 and another pepper field trial is required in Zone 2. Provided that two more acceptable tests are submitted on tomato (1 test in Zone 1) and pepper (1 test in Zone 2), tomato and pepper field trial data would support the use of three broadcast foliar applications of abamectin, formulated as a 0.7 lb ai/gal SC, on fruiting vegetables at up to 0.019 lb ai/A/application, for a total of 0.056 lb ai/A/season. The data also support a minimum RTI of 7 days and a minimum PHI of 7 days.

E. REFERENCES

DP Number: 203373

Subject: Abamectin (Avermectin B₁) for Use in/on the Cucurbit Crop Group (Cucumbers, Melons and Squash). Evaluation of Analytical Methodology and Residue Data.

From: G. Herndon

To: G. LaRocca, L. Arrington and J. Smith

Dated: 3/29/95

MRID(s): 43203801 and 43228601

F. DOCUMENT TRACKING

RDI: Nancy Dodd (1/21/10); ChemTeam (1/21/10); Leung Cheng (1/21/10)

Petition Number: NA

DP#s: 364734 and 364737

PC Code: 122804

Template Version June 2005

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Primary Evaluator

Nancy Dodd

Nancy Dodd, Chemist, RAB III/HED (7509P)

Date: 1/21/10

Approved by

Leung Cheng

Leung Cheng, Senior Chemist, RAB III/HED (7509P)

Date: 1/21/10

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B, Durham, NC 27713; submitted 09/30/2009). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47702806. Hamilton, L. (2009) Abamectin - Magnitude of the Residues in or on Tomatoes and Peppers, including Processing as Representative Commodities of Vegetables, Fruiting, Group 8, Final Report: Project Number: T001871/07. ML08/1460/SYN. Unpublished study prepared by Syngenta Crop Protection, Inc. and Morse Laboratories, Inc. 302 pages.

EXECUTIVE SUMMARY:

Syngenta Crop Protection submitted tomato processing data supporting the use of abamectin, formulated as a 0.7 lb ai/gal suspension concentrate (SC), on fruiting vegetables. In two field trials conducted in Zone 10 during 2008, abamectin (0.7 lb ai/gal SC) was applied to two separate plots of tomatoes in each trial as three broadcast foliar applications at rates of 0.019-0.020 lb ai/A or 0.094-0.098 lb ai/A and retreatment intervals (RTIs) of 6-7 days, for totals of 0.057-0.058 lb ai/A (1x rate) or 0.28-0.29 lb ai/A (5x rate). Applications were made during the later stages of fruit development, using ground equipment in volumes of 30-33 gal/A, and all applications included the use of a non-ionic surfactant (NIS) as an adjuvant at 0.1-1.5% v/v.

Single bulk control and treated samples of tomatoes were harvested from each test 7 days after the last application (DAT), and shipped on the day of harvest under ambient conditions to the processing facility. Samples of whole fruit were collected and frozen at the processor, and the bulk tomato samples from each test were processed within 6 days of harvest into puree and paste using simulated commercial procedures. Samples of puree and paste were collected and frozen, and all samples were stored at -20°C for up to 6 months prior to analysis, an interval which is supported by the available storage stability data.

Samples were analyzed for total abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) using a liquid chromatography/tandem mass spectrometry (LC/MS/MS) method (Morse Labs Method No. Meth-192, revision 2). For this method, residues were extracted with acetonitrile:0.1% phosphoric acid (25:75) and cleaned up by partitioning into hexane and elution through a solid phase extraction (SPE) cartridge. The purified residues were then analyzed by LC/MS/MS, with each analyte being detected and quantified separately. The validated limit of quantitation (LOQ) is 0.002 ppm for each analyte. Although the LC/MS/MS method determines



avermectin B_{1a} and 8,9-Z avermectin B_{1a} separately, residues for these two analytes were reported as the combined B_{1a} residues (B_{1a} + 8,9-Z B_{1a}).

Following three broadcast foliar applications of abamectin (SC) at 1x rates, combined abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) were <0.004 ppm in/on whole tomatoes harvested at 7 DAT from both tests. Residues were also <0.004 ppm in puree and paste from the 1x tests; therefore, processing factors for the 1x tests could not be calculated.

In the two 5x rate tests, combined abamectin residues were 0.019 and 0.007 ppm in/on whole tomatoes. Residues in the associated puree fractions were 0.009 and <0.004 ppm, respectively, for processing factors of 0.47x and 0.57x. Residues in the associated paste fractions were 0.022 and 0.005 ppm, respectively, for processing factors of 1.16x and 0.71x. The average processing factors for tomato were 0.52x for puree and 0.94x for paste, indicating that abamectin residues do not concentrate in tomato puree or paste. The maximum theoretical concentration factor for tomatoes is 5.5x (paste).

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP# 364734.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Tolerances are established for the combined residues of avermectin B₁ [a mixture of avermectins containing ≥80% avermectin B_{1a} (5-O-demethyl avermectin A₁) and ≤20% avermectin B_{1b} (5-O-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A₁)] and its delta-8,9-isomer. Abamectin is a natural fermentation product of the soil bacterium *Streptomyces avermitilis*. Abamectin is an insecticide/miticide used to control mites, leafminers, and other insects in commercially important crops, as a seed protectant against nematodes, and in veterinary medicine for treatment of internal and external parasites and mites.

To support registrations for new SC formulations containing abamectin, Syngenta has submitted processing data on tomato. The chemical structure and nomenclature of abamectin and the physicochemical properties of the technical grade of abamectin are presented in Tables A.1 and A.2.



TABLE A.1. Test Compound Nomenclature.

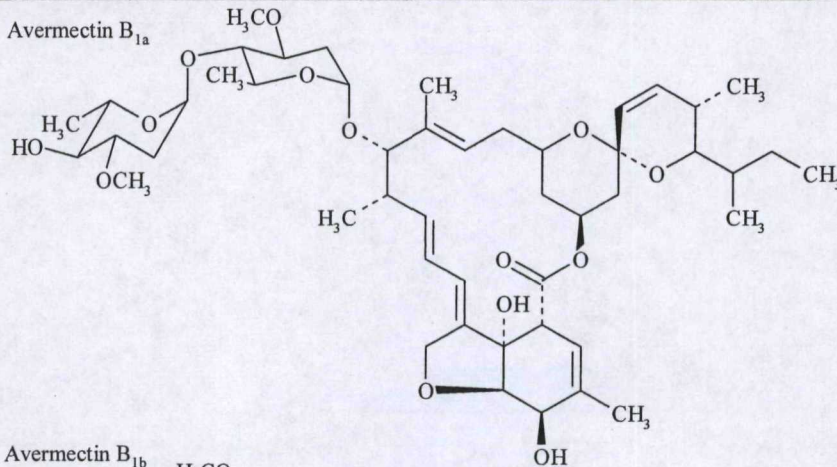
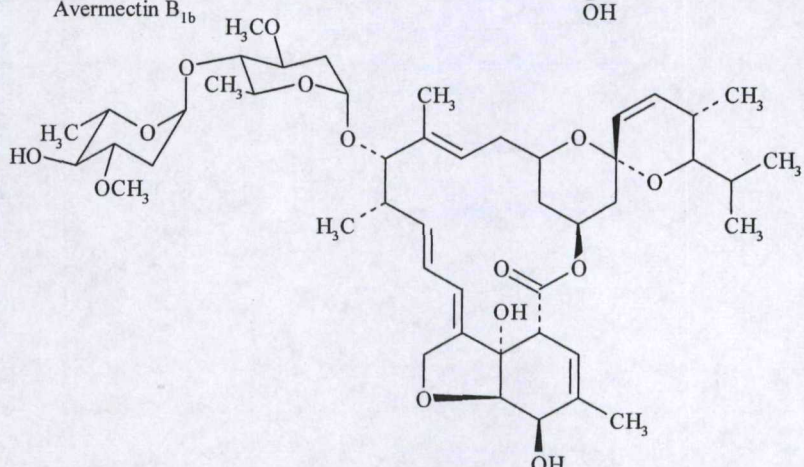
Compound	<div><p>Avermectin B_{1a}</p><p>Avermectin B_{1b}</p></div>
Common name	Abamectin; Avermectin B ₁
Company experimental name	MK-0936
IUPAC name	mixture of (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> ,22 <i>Z</i>)-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i>)-6'-[(<i>S</i>)- <i>sec</i> -butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 ^{4,8} .0 ^{20,24}]-pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-4- <i>O</i> -(2,6-dideoxy-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranosyl)-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranoside and (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> ,22 <i>Z</i>)-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i>)-21,22-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 ^{4,8} .0 ^{20,24}]-pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-4- <i>O</i> -(2,6-dideoxy-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranosyl)-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranoside
CAS name	Avermectin B ₁
CAS registry number	71751-41-2
End-use product (EP)	Agri-Mek SC (0.7 lb ai/gal SC)



TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound Abamectin.			
Parameter	Value	Reference	
Melting point/range	161.8-1.69.4 °C	Study report (MRID 47702806)	
pH	8-9 at 25°C		
Density	1.18 x 10 ³ kg/m ³ at 22 °C		
Water solubility at 25 °C	1.21 µg/mL at pH 7.57		
Solubility in organic solvents	Acetone		72 g/L
	Dichloromethane		470 g/L
	Ethyl acetate		160 g/L
	Hexane		0.110 g/L
	Methanol		13 g/L
	Octanol	83 g/L	
Toluene	23 g/L		
Vapor pressure at 25 °C	<3.7 x 10 ⁻⁶ Pa		
Dissociation constant (pK _a)	no dissociation constant in aqueous solution		
Octanol/water partition coefficient, Log P	4.4 at pH 7.2		
UV/visible absorption spectrum	Absorbance maxima Neutral : 32,549 l/mol•cm at 245 nm 18,983 l/mol•cm at 255 nm Acidic: 34,515 l/mol•cm at 245 nm 20,977 l/mol•cm at 255 nm Basic: 29,551 l/mol•cm at 245 nm		

B. EXPERIMENTAL DESIGN

B.1. Application and Crop Information

To provide samples for the processing studies, two tomato field trials were conducted in Zone 10 during the 2008 growing season. Two plots of tomatoes were treated at each field site, one at the reported 1x rate and the second at an exaggerated 5x rate. At each site, a 0.7 lb ai/gal SC formulation of abamectin was applied to tomatoes as three broadcast foliar applications at rates of 0.019-0.020 lb ai/A (1x rate) or 0.094-0.098 lb ai/A (5x rate) and at RTIs of 6-7 days. The total seasonal rates were 0.057-0.058 lb ai/A (1x rate) and 0.28-0.29 lb ai/A (5x rate). Applications were made during the later stages of fruit development, using ground equipment in volumes of 30-33 gal/A, and included the use of a NIS as an adjuvant at 0.1-0.5% v/v. Actual test parameters are reported in Table B.1.1.

The actual temperature recordings and rainfall averages were comparable to average historical values for the study period. Irrigation was used to supplement rainfall as needed. Information on applications of fertilizer and other maintenance pesticides were also provided for each trial site.



TABLE B.1.1. Study Use Pattern							
Location (County, State; Year) Trial ID	End-use product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (gal/A)	Rate (lb ai/A)	RTI ¹ (days)	Total Rate (lb ai/A)	
Porterville CA 2008 W32CA078448	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 85-89	30-33	0.019-0.020	6	0.058	NIS 0.1% v/v
				0.095-0.098	6	0.29	
Huron, CA 2008 W32CA078450	0.7 lb ai/gal SC	Three broadcast foliar applications at BBCH 81-89	31-32	0.019	7	0.057	NIS 0.5% v/v
				0.094-0.096	7	0.28	

¹ RTI = Retreatment Interval

B.2. Sample Handling and Processing Procedures

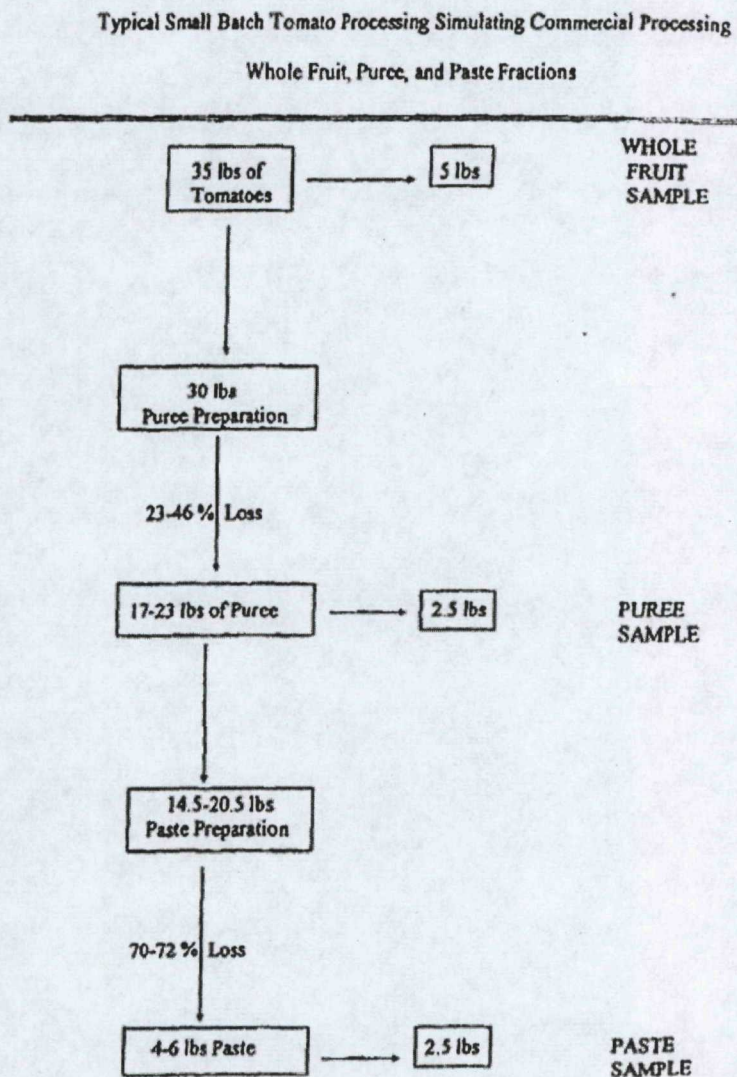
Single control and treated samples of mature tomatoes (≥ 75 lb/sample) were harvested from each site 7 DAT. Samples were shipped by overnight courier directly to the processing facility (A.C.D.S. Research, Inc., North Rose, NY) under ambient condition on the day of harvest. After arrival at the processing facility, subsamples of whole fruit were collected from each test, and the remaining fruits were processed within 6 days into puree and paste using simulated commercial practices. A flowchart of the processing procedures, which were copied without alteration from MRID 47702806, is presented in Figure B.2.

Samples of whole fruit and each processed fraction were frozen immediately after collection. Samples of each frozen processed fraction were shipped on dry ice by overnight courier to Syngenta (Greensboro, NC). At Syngenta, the samples were prepared for analysis by homogenization with dry ice and were then stored at -20°C until shipment by overnight courier on dry ice to the analytical laboratory (Morse Laboratories, Sacramento, CA). Samples of whole fruits were shipped frozen by overnight courier from the processing facility directly to the analytical laboratory, where the samples were homogenized with dry ice. All samples were stored at $-20 \pm 5^{\circ}\text{C}$ at the analytical laboratory until analysis.

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FIGURE B.2. Processing Flowchart for Tomatoes.



B.3. Analytical Methodology

Samples of whole tomatoes, purée and paste were analyzed for residues of abamectin (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) using an LC/MS/MS method, Morse Analytical Method, Meth-192/revision 2, "Determination of Abamectin Residues in Fruits and Vegetables (Raw Agricultural Commodity) by LC/MS/MS." This method uses extraction and purification procedures similar to the current tolerance enforcement methods, but uses MS/MS analysis rather than fluorescence detection.

Abamectin residues were extracted with acetonitrile:0.1% phosphoric acid (25:75), and the residues were partitioned into hexane and dried over anhydrous Na₂SO₄. Residues were then purified by elution through an aminopropyl SPE cartridge with ethyl acetate:methanol (72:25, v/v). Residues in the elute fraction were concentrated to dryness and redissolved in acetonitrile



for LC/MS/MS analysis. The LC system utilized a reverse phase C_{18} column with a mobile phase gradient of water:100 mM NH_4OAc in methanol (95:5, v/v) to 5 mM NH_4OAc in methanol. This method separately detects and quantifies all three analytes. The 895.5→751.5 m/z transition was used for detection and quantitation of avermectin B_{1a} and 8,9-Z avermectin B_{1a} , and the 881.2→737.0 m/z transition was used for detection and quantitation of avermectin B_{1b} . The validated LOQ for this method is 0.002 ppm for each analyte, and the LOD was not reported. Although the LC/MS/MS method determines avermectin B_{1a} and 8,9-Z avermectin B_{1a} separately, residues for these two analytes were reported as the combined B_{1a} residues ($B_{1a} + 8,9-Z B_{1a}$).

The method was validated in conjunction with the analysis of the processing study samples. Control samples of tomatoes were fortified with avermectin B_{1a} at 0.002-0.10 ppm, avermectin B_{1b} at 0.002-0.006 ppm, and 8,9-Z avermectin B_{1a} at 0.002 and 0.033 ppm. Control samples of tomato puree and paste were fortified with avermectin B_{1a} at 0.002-0.05 ppm and avermectin B_{1b} at 0.002 and 0.003 ppm.

C. RESULTS AND DISCUSSION

The LC/MS/MS method used to determine residues of avermectin B_{1a} , avermectin B_{1b} , and 8,9-Z avermectin B_{1a} was adequately validated in conjunction with the analysis of the processing study samples. For whole tomatoes, the overall average recoveries (\pm S.D.) were $98 \pm 13\%$ for avermectin B_{1a} , $91 \pm 15\%$ for avermectin B_{1b} , and 95% for 8,9-Z avermectin B_{1a} (Table C.1). For tomato puree, the overall average recoveries (\pm S.D.) were $100 \pm 11\%$ for avermectin B_{1a} and $110 \pm 15\%$ for avermectin B_{1b} . For tomato paste, the overall average recoveries (\pm S.D.) were $94 \pm 13\%$ for avermectin B_{1a} and $79 \pm 15\%$ for avermectin B_{1b} . Adequate sample chromatograms and example calculations were provided. Apparent residues of each analyte were <LOQ in/on all untreated samples. Concurrent fortifications adequately bracketed field trial residue results.

Sample of whole tomatoes, puree and paste were stored frozen up to 6 months prior to extraction for analysis (Table C.2). Adequate storage stability data have been submitted previously indicating that residues of avermectin B_{1a} , avermectin B_{1b} , and 8,9-Z avermectin B_{1a} are stable under frozen storage for 24 months in celery, strawberries, and tomatoes; 29 months in oranges, lemons, and grapefruit; and 35 months in pears (DP#203373, G. J. Herndon, 3/29/95). These data adequately support the sample storage conditions and durations in the tomato processing studies.

Following three broadcast foliar applications of abamectin (SC) at 1x rates, combined abamectin residues (avermectin B_{1a} , 8,9-Z avermectin B_{1a} , and avermectin B_{1b}) were all <0.004 ppm in/on samples of whole tomatoes harvested at 7 DAT from both tests and were also <0.004 ppm in samples of puree and paste processed from the 1x treated fruits (Table C.3). Therefore, processing factors for the 1x tests could not be calculated. However, quantifiable abamectin residues were found in tomatoes from the 5x tests.

For the Porterville, CA field trial, combined abamectin residues in/on whole tomatoes averaged 0.019 ppm following 5x applications, and the residues in the associated puree and paste fractions



averaged 0.009 and 0.022 ppm, respectively, for processing factors of 0.47x and 1.16x. For the Huron, CA field trial, combined abamectin residues in/on whole tomatoes averaged 0.007 ppm following 5x applications, and residues in the associated puree and paste fractions averaged <0.004 and 0.005 ppm, respectively, for processing factors of 0.57x and 0.71x. For both 5x tests, the average processing factors were 0.52x for puree and 0.94x for paste. The maximum theoretical concentration factor for tomatoes is 5.5x (paste).

TABLE C.1. Summary of Concurrent Recoveries of Abamectin from Tomato and Tomato Processed Products using an LC/MS/MS Method.				
Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean \pm Std. Dev. (%)
Avermectin B_{1a}				
Tomato	0.002	14	75, 81, 82, 86, 96, 98, 101, 102, 109, 109, 110, 114, 117, 119	100 \pm 14
	0.03	11	77, 80, 83, 91, 93, 99, 100, 100, 107, 107, 111	95 \pm 11
	0.05	2	96, 113	105
	0.10	1	100	100
	Overall	28	75-119	98 \pm 13
Tomato Paste	0.002	3	82, 98, 102	94 \pm 11
	0.003	2	80, 91	86
	0.05	1	113	113
	Overall	6	82-113	94 \pm 13
Tomato puree	0.002	3	86, 101, 119	102 \pm 17
	0.03	2	100, 100	100
	0.05	1	96	96
	Overall	6	86-119	100 \pm 11
Avermectin B_{1b}				
Tomato	0.002	11	66, 69, 72, 75, 76, 86, 89, 99, 100, 105, 112	86 \pm 16
	0.003	2	97, 114	106
	0.006	1	105	105
	Overall	14	66-114	91 \pm 15
Tomato Paste	0.002	2	69, 72	71
	0.003	1	97	97
	Overall	3	69-97	79 \pm 15
Tomato puree	0.002	2	112, 105	109
	0.003	1	114	114
	Overall	3	105-114	110 \pm 5
8,9-Z Avermectin B_{1a}				
Tomato	0.002	1	87	95
	0.03	1	103	



TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration (months) ¹	Interval of Demonstrated Storage Stability (months) ²
Tomato fruit, paste and puree	-20 ± 5	2-6	24 - tomatoes

¹ Interval from harvest to analysis. Extracts were stored 0-10 days prior to analysis.

² Storage stability data are available for tomatoes stored for 24 months (DP# 203373, G. Herndon, 3/29/95).

TABLE C.3. Residue Data from Tomato Processing Study with Abamectin (SC).

Location (County, State; Year) Trial ID	RAC	Total Rate (lb ai/A)	Commodity	PHI (days)	Total Abamectin Residues (ppm) ¹		Processing Factor
					Replicates	Average	
Porterville CA 2008 W32CA078448	Tomato	0.058 (1x rate)	Fruit (RAC)	7	<0.004, <0.004, <0.004	<0.004	NA ²
			Puree	7	<0.004, <0.004, <0.004	<0.004	NC ³
			Paste	7	<0.004, <0.004, <0.004	<0.004	NC
		0.29 (5x rate)	Fruit (RAC)	7	0.022, 0.022, 0.012	0.019	NA
			Puree	7	0.009, 0.009	0.009	0.47x
			Paste	7	0.022, 0.022	0.022	1.16x
Huron, CA 2008 W32CA078450	Tomato	0.057 (1x rate)	Fruit (RAC)	7	<0.004, <0.004, <0.004	<0.004	NA
			Puree	7	<0.004, <0.004, <0.004	<0.004	NC
			Paste	7	<0.004, <0.004, <0.004	<0.004	NC
		0.28 (5x rate)	Fruit (RAC)	7	0.008, 0.008, 0.006r	0.007	NA
			Puree	7	<0.004, <0.004	<0.004	0.57x
			Paste	7	0.004, 0.005	0.005	0.71x

¹ Total residues of avermectin B_{1a}, avermectin B_{1b} and 8,9-Z avermectin B_{1a}. The combined LOQ is 0.004 ppm for each tomato commodity.

² NA = not applicable

³ NC = not calculated, as residues were <LOQ in whole fruit and each processed fraction.

D. CONCLUSION

The submitted tomato processing studies are adequate. An acceptable method was used for quantitation of abamectin residues and the sample storage conditions and durations are supported by adequate storage stability data. Although residues were <LOQ in the whole tomatoes from the 1x tests, combined abamectin residues were >LOQ from the two 5x tests; therefore, processing factors for puree and paste could be calculated. The average processing factors for total abamectin residues were 0.52x in puree and 0.94x in paste. These data indicate that abamectin residues do not concentrate in tomato processed fractions.



E. REFERENCES

DP Number: 203373
Subject: Abamectin (Avermectin B₁) for Use in/on the Cucurbit Crop Group (Cucumbers, Melons and Squash). Evaluation of Analytical Methodology and Residue Data.
From: G. Herndon
To: G. LaRocca, L. Arrington and J. Smith
Dated: 3/29/95
MRIDs: 43203801 and 43228601

F. DOCUMENT TRACKING

RDI: Nancy Dodd (1/21/10); RAB3 ChemTeam (1/21/10); Leung Cheng (1/21/10)
Petition Number: NA
DP#s: 364734 and 364737
PC Code: 122804

Template Version June 2005

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Primary Evaluator Nancy Dodd Date: 1/21/10
Nancy Dodd, Chemist, RAB III/HED (7509P)
Approved by Leung Cheng Date: 1/21/10
Leung Cheng, Senior Chemist, RAB III/HED (7509P)

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B, Durham, NC 27713; submitted 09/30/2009). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47702807. Hamilton, L. (2008) Abamectin - Magnitude of the Residues in or on Oranges, Grapefruit and Lemon as Representative Commodities of citrus, group 10: Final Report: Project Number: T001869/07, M073/1, 192. Unpublished study prepared by Syngenta Crop Protection, Inc. 304 pages.

EXECUTIVE SUMMARY:

Syngenta Crop Protection submitted field trial data supporting the use of abamectin, formulated as a 0.7 lb ai/gal suspension concentrate (SC), on citrus fruits. During the 2007 growing season, twelve orange and six grapefruit field trials were conducted in Zones 3, 6 and 10, and five lemon field trials were conducted in Zones 3 and 10. At each site, abamectin (0.7 lb ai/gal SC) was applied to citrus trees as two broadcast foliar applications during the later stages of fruit development at rates of 0.022-0.025 lb ai/A and at retreatment intervals (RTIs) of 28-31 days, for a total of 0.046-0.049 lb ai/A/season. All applications were made using ground equipment and included the use of a horticultural oil as an adjuvant at 0.1-1.0% v/v. Low volume applications (10-97 gal/A) were used in 13 of the trials and high volume applications (109-270 gal/A) were used in the remaining 10 trials.

Single control and duplicate treated samples of each citrus fruit were harvested from each test 7 days after the second application (DAT). In two of the lemon trials, single treated samples were also collected at 0, 3, 5 and 10 DAT to assess residue decline. The citrus fruit samples were stored at -20°C for up to 5 months prior to extraction for analysis, an interval which is supported by the available storage stability data.

Samples were analyzed for total abamectin residues (avermectin B_{1a}, 8,9-Z avermectin B_{1a}, and avermectin B_{1b}) using either a high performance liquid chromatography/fluorescence detection (HPLC/FLD) method (Method No. M-073.1) or a liquid chromatography/tandem mass spectrometry (LC/MS/MS) method (Method No. Meth-192, rev. 2). For both methods, residues were extracted with acetonitrile:0.1% phosphoric acid (25:75) and cleaned up by partitioning into hexane and elution through a solid phase extraction (SPE) cartridge. For Method No. M-073.1, the purified residues were derivatized with trifluoroacetic anhydride and analyzed by HPLC/FLD, which determines avermectin B_{1a} and 8,9-Z avermectin B_{1a} as a single component



and avermectin B_{1b} separately. For Method Meth-192/rev.2, the purified residues were analyzed directly by LC/MS/MS, with each analyte being detected and quantified separately. The validated limit of quantitation (LOQ) for both methods is 0.002 ppm for each analyte.

Following two foliar applications of abamectin (SC) at rates totaling 0.047-0.049 lb ai/A, total B_{1a} residues (B_{1a} + 8,9-Z B_{1a}) were <0.002-0.004 ppm in/on oranges, <0.002 ppm in/on grapefruits, and <0.002-0.006 ppm in/on lemons harvested at 7 DAT. For samples analyzed using the HPLC/MS/MS method (6 orange samples, 2 grapefruit samples and 2 lemon samples), residues of 8,9-Z avermectin B_{1a} were <0.002 ppm in each sample. Residues of avermectin B_{1b} were also <0.002 ppm in/on all samples of oranges, grapefruits and lemons.

Total abamectin residues in/on citrus fruits harvested at 7 DAT were <0.004-0.006 ppm in/on oranges, <0.004 ppm in/on grapefruits, and <0.004-0.008 ppm in/on lemons. Average total residues were 0.004 ppm for oranges and grapefruits and 0.005 ppm for lemons. The total highest average field trial (HAFT) residues were 0.005 ppm for oranges, 0.004 ppm for grapefruits, and 0.007 ppm for lemons. There was no notable difference in residue values between the dilute and concentrated application volumes.

In both lemon residue decline tests, total abamectin residues declined from 0.009 or 0.012 ppm at 0 DAT to <0.004 ppm by 10 DAT, indicating that abamectin residues decline at longer post-treatment intervals.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the citrus fruit field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP# 364734.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Tolerances are established for the combined residues of avermectin B₁ [a mixture of avermectins containing ≥80% avermectin B_{1a} (5-*O*-demethyl avermectin A₁) and ≤20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A₁)] and its delta-8,9-isomer. Abamectin is a natural fermentation product of the soil bacterium *Streptomyces avermitilis*. Abamectin is an insecticide/miticide used to control mites, leafminers, and other insects in commercially important crops, as a seed protectant against nematodes, and in veterinary medicine for treatment of internal and external parasites and mites.



To support registrations for new SC formulations containing abamectin, Syngenta has submitted field trial data on citrus fruits. The chemical structure and nomenclature of abamectin and the physicochemical properties of the technical grade of abamectin are presented in Tables A.1 and A.2.

TABLE A.1. Test Compound Nomenclature.

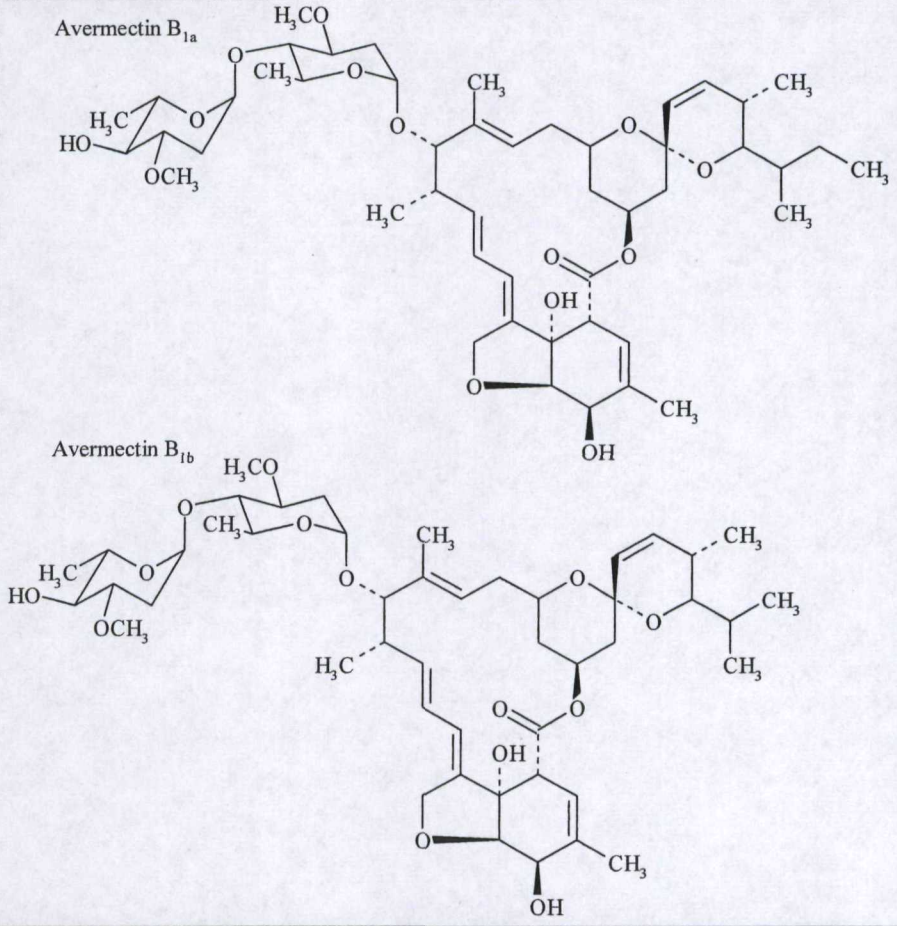
Compound	
	
Common name	Abamectin; Avermectin B ₁
Company experimental name	MK-0936
IUPAC name	mixture of (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> ,22 <i>Z</i>)-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i>)-6'-[(<i>S</i>)- <i>sec</i> -butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 ^{4,8} .0 ^{20,24}]pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-4- <i>O</i> -(2,6-dideoxy-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranosyl)-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranoside and (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> ,22 <i>Z</i>)-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i>)-21,22-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 ^{4,8} .0 ^{20,24}]pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-4- <i>O</i> -(2,6-dideoxy-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranosyl)-3- <i>O</i> -methyl- α - <i>L</i> -arabino-hexopyranoside
CAS name	Avermectin B ₁
CAS registry number	71751-41-2
End-use product (EP)	Agri-Mek SC (0.7 lb ai/gal SC)



TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound Abamectin.		
Parameter	Value	Reference
Melting point/range	161.8-169.4 °C	Study report (MRID 47702807)
pH	8-9 at 25°C	
Density	1.18 x 10 ³ kg/m ³ at 22°C	
Water solubility at 25 °C	1.21 µg/mL at pH 7.57	
Solubility in organic solvents	Acetone	72 g/L
	Dichloromethane	470 g/L
	Ethyl acetate	160 g/L
	Hexane	0.110 g/L
	Methanol	13 g/L
	Octanol	83 g/L
	Toluene	23 g/L
Vapor pressure at 25 °C	<3.7 x 10 ⁻⁶ Pa	
Dissociation constant (pK _a)	no dissociation constant in aqueous solution	
Octanol/water partition coefficient, Log P	4.4 at pH 7.2	
UV/visible absorption spectrum	Absorbance maxima Neutral : 32,549 l/mol•cm at 245 nm 18,983 l/mol•cm at 255 nm Acidic: 34,515 l/mol•cm at 245 nm 20,977 l/mol•cm at 255 nm Basic: 29,551 l/mol•cm at 245 nm	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Field trial data were submitted from 12 orange tests, six grapefruit tests, and five lemon tests conducted during the 2007 growing season. The orange and grapefruit field trials were conducted in Zones 3, 6 and 10, and the lemon field trials were conducted in Zones 3 and 10. Trial site conditions are presented in Table B.1.1. The crop varieties grown are identified in Table C. 3.

At each site, a 0.7 lb ai/gal SC formulation of abamectin was applied to citrus trees as two broadcast foliar applications at rates of 0.022-0.025 lb ai/A and RTIs of 28-31 days, for a total of 0.046-0.049 lb ai/A/season. Applications were made during the later stages of fruit development, using ground equipment. Low application volumes (Trt# 2; 10-97 gal/A) were used in 13 of the trials, and high application volumes (Trt# 3; 109-270 gal/A) were used in 10 of the trials. All applications included the use of a horticultural oil as an adjuvant at 0.1-1.0% v/v. Actual test parameters are reported in Table B.1.2.

The actual temperature recordings and rainfall averages were comparable to average historical values for the study period. Irrigation was used to supplement rainfall as needed. Information on applications of fertilizer and other maintenance pesticides were also provided for each trial site.

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**TABLE B.1.1. Trial Site Conditions.**

Trial Identification (City, State; Year)	Soil characteristics			
	Type	% OM	pH	CEC (meq/100g)
Haines City, FL 2007 E14FL078338	Sand	0.6	6.9	4.4
Groveland, FL 2007 E14FL078339	Sand	1.1	5.9	5.1
Bradenton, FL 2007 E16FL078340	Sand	1.9	6.4	2.8
Bradenton, FL 2007 E16FL078341	Sand	1.9	6.4	2.8
Bradenton, FL 2007 E16FL078342	Sand	1.9	6.4	2.8
Bradenton, FL 2007 E16FL078343	Sand	1.9	6.4	2.8
DeLeon Springs, FL 2007 E13FL078344	Sand	2.1	5.8	7.9
DeLeon Springs, FL 2007 E13FL078345	Sand	2.1	5.8	7.9
Fort Pierce, FL 2007 E15FL078346	Sand	0.7	6.3	4.5
Groveland, FL 2007 E14FL078347	Sand	1.3	6.2	5.8
Haines City, FL 2007 E14FL078348	Sand	1.1	6.9	4.9
Bradenton, FL 2007 E16FL078349	Sand	1.7	6.0	2.6
Alamo, TX 2007 W08TX078350	Sandy Clay Loam	0.9	7.7	19.6
Alamo, TX 2007 W08TX078351	Sandy Clay Loam	0.9	7.7	19.6
Porterville, CA 2007 W32CA078352	Loam	2.0	7.8	26.3
Strathmore, CA 2007 W32CA078353	Clay Loam	1.4	7.8	32.3
Sanger, CA 2007 W30CA078354	Sandy Loam	1.3	7.3	7.3
Porterville, CA 2007 W32CA078355	Clay	2.6	6.6	40.1
Sanger, CA 2007 W30CA078356	Sandy Clay Loam	0.97	6.8	24.1
Elderwood, CA 2007 W30CA078357	Sandy Loam	1.10	7.8	9.1
Richgrove, CA 2007 W32CA078358	Clay Loam	1.1	8.1	42.4
Lindsay, CA 2007 W32CA078359	Clay Loam	1.6	6.8	19.3
Elderwood, CA 2007 W30CA078360	Sandy Loam	1.10	7.8	9.1

**TABLE B.1.2. Study Use Pattern.**

Location (City, State; Year) Trial ID	End-Use Product	Application Information						Tank Mix/ Adjuvants
		Method; Timing	TRT# ¹	Volume (gal/A)	Single Rates (lb ai/A)	RTI ² (days)	Total Rate (lb ai/A)	
Orange Field Trials								
Haines City, FL 2007 E14FL078338	0.7 lb ai/gal SC	Two broadcast foliar applications during late fruit development	2	29-31	0.023-0.024	30	0.047	Horticultural oil 1% v/v
Groveland, FL 2007 E14FL078339	0.7 lb ai/gal SC	Two broadcast foliar applications during late fruit development	3	254- 259	0.022-0.023	30	0.046	Horticultura oil 1% v/v
Bradenton, FL 2007 E16FL078340	0.7 lb ai/gal SC	Two broadcast foliar applications to ripe fruit	2	83-85	0.024-0.025	31	0.049	Horticultural oil 0.25% v/v
Bradenton, FL 2007 E16FL078341	0.7 lb ai/gal SC	Two broadcast foliar applications to ripe fruit	3	269- 270	0.023	30	0.046	Horticultural oil 0.25% v/v
Bradenton, FL 2007 E16FL078342	0.7 lb ai/gal SC	Two broadcast foliar applications to ripe fruit	2	83-84	0.024	28	0.048	Horticultural oil 0.25% v/v
Bradenton, FL 2007 E16FL078343	0.7 lb ai/gal SC	Two broadcast foliar applications to ripe fruit	3	262- 264	0.023	28	0.046	Horticultural oil 0.1% v/v
DeLeon Springs, FL 2007 E13FL078344	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 87-89	2	55-62	0.024	30	0.047	Horticultural oil 1% v/v
DeLeon Springs, FL 2007 E13FL078345	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 83-85	3	109- 128	0.023	30	0.046	Horticultural oil 0.1% v/v
Alamo, TX 2007 W08TX078350	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 83-85	2	78-79	0.023-0.024	29	0.047	Horticultural oil 0.5% v/v
Porterville, CA 2007 W32CA078352	0.7 lb ai/gal SC	Two broadcast foliar applications BBCH 85- 89	2	88-91	0.023	30	0.046	Horticultural oil 1% v/v
Strathmore, CA 2007 W32CA07853	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 85-89	3	199- 201	0.023	30	0.046	Horticultural oil 1% v/v
Sanger, CA 2007 W30CA078354	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 81	2	10	0.023-0.024	30	0.047	Horticultural oil 0.5% V/V
Grapefruit Field Trials								
Groveland, FL 2007 E14FL078347	0.7 lb ai/gal SC	Two broadcast foliar applications during late fruit development	2	34-35	0.022-0.023	29	0.046	Horticultural oil 1% v/v
Haines City, FL 2007 E14FL078348	0.7 lb ai/gal SC	Two broadcast foliar applications to mature fruit	3	258	0.023-0.024	29	0.047	Horticultural oil 1% v/v
Bradenton, FL 2007 E16FL078349	0.7 lb ai/gal SC	Two broadcast foliar applications to ripe fruit	2	82-83	0.024	31	0.048	Horticultural oil 0.25% v/v



TABLE B.1.2. Study Use Pattern.

Location (City, State; Year) Trial ID	End-Use Product	Application Information						Tank Mix/ Adjuvants
		Method; Timing	TRT# ¹	Volume (gal/A)	Single Rates (lb ai/A)	RTI ² (days)	Total Rate (lb ai/A)	
Alamo, TX 2007 W08TX078351	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 83-85	3	260- 265	0.023	30	0.046	Horticultural oil 0.5% v/v
Lindsay, CA 2007 W32CA078359	0.7 lb ai/gal SC	Two broadcast foliar applications BBCH 85- 89	2	88-92	0.023	30	0.046	Horticultural oil 1% v/v
Elderwood, CA 2007 W30CA078360	0.7 lb ai/gal SC	Two broadcast foliar applications BBCH 85- 88	3	200- 201	0.023	30	0.046	Horticultural oil 0.5% v/v
Lemon Field Trials								
Fort Pierce, FL 2007 E15FL078346	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 73-75	2	95-97	0.024	28	0.047	Horticultural oil 3.2% v/v
Porterville, CA 2007 W32CA078355	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 81-89	2	88-92	0.023	30	0.046	Horticultural oil 1% v/v
Sanger, CA 2007 W30CA078356	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 79-81	3	199- 201	0.023	30	0.046	Horticultural oil 0.5% v/v
Elderwood, CA 2007 W30CA078357	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 79-81	2	75-76	0.023	30	0.046	Horticultural oil 0.5% v/v
Richgrove, CA 2007 W32CA078358	0.7 lb ai/gal SC	Two broadcast foliar applications at BBCH 85-89	3	180- 181	0.023	28	0.046	Horticultural oil 1% v/v

¹ Trt #2 used low volume or concentrated applications (10-97 gal/A) and Trt #3 used high volume or dilute applications (109-270 gal/A).

² RTI = Retreatment Interval



TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones ²	Oranges			Lemons			Grapefruit		
	Submitted	Requested ¹		Submitted	Requested ¹		Submitted	Requested ¹	
		Canada	U.S.		Canada	U.S.		Canada	U.S.
1	--	NA	--	--	NA	--	--	NA	--
2	--	NA	--	--	NA	--	--	NA	--
3	8	NA	8	1	NA	1	3	NA	3
4	--	NA	--	--	NA	--	--	NA	--
5	--	NA	--	--	NA	--	--	NA	--
6	1	NA	1	--	NA	--	1	NA	1
7	--	NA	--	--	NA	--	--	NA	--
8	--	NA	--	--	NA	--	--	NA	--
9	--	NA	--	--	NA	--	--	NA	--
10	3	NA	3	4	NA	4	2	NA	2
11	--	NA	--	--	NA	--	--	NA	--
12	--	NA	--	--	NA	--	--	NA	--
13	--	NA	--	--	NA	--	--	NA	--
Total	12	NA	12	5	NA	5	6	NA	6

¹ Field trials required for a crop group tolerance

² Regions 1A, 5A, 5B, 7A and 14-21 were not included as the proposed use is for the U.S. only.

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of citrus fruits (≥ 5 lb/sample) were harvested from the appropriate tests at 7 DAT. In two of the lemon trials, single treated samples were also harvested at 0, 3, 5 and 10 DAT to assess residue decline. All samples were frozen at the field sites (time to freezer not reported) and shipped frozen within 4-36 days of harvest, via ACDS freezer truck or on dry ice by overnight courier, to Syngenta (Greensboro, NC). Samples were prepared for analysis by homogenization with dry ice and were stored at -20°C until shipment by overnight courier on dry ice to the analytical laboratory (Morse Laboratories, Sacramento, CA). Samples were stored at $-20 \pm 5^{\circ}\text{C}$ at the analytical laboratory until analysis.

B.3. Analytical Methodology

Citrus fruit samples were analyzed for abamectin residues using either a HPLC/FLD method or a LC/MS/MS method. The HPLC/FLD method (Novartis Method No. M-073.1; "HPLC-Fluorescence Method for the Quantitation of Avermectin B₁ and 8.9-Z Avermectin B₁ in/on Fruits and Vegetables") is similar to the current tolerance enforcement method. The LC/MS/MS method (Morse Analytical Method No. Meth-192/revision 2; "Determination of Abamectin Residues in Fruits and Vegetables (Raw Agricultural Commodity) by LC/MS/MS"), utilizes the same sample extraction and purification procedures as the HPLC/FLD method, but does not include a derivatization step and uses MS/MS detection for analysis.

For both methods, abamectin residues (avermectin B_{1a}, 8.9-Z avermectin B_{1a}, and avermectin B_{1b}) were extracted with acetonitrile:0.1% phosphoric acid (25:75). Residues were partitioned into hexane, dried over anhydrous Na₂SO₄, and purified by elution through an aminopropyl SPE

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cartridge with ethyl acetate:methanol (72:25, v/v). Residues were then concentrated to dryness and redissolved in acetonitrile for HPLC/FLD or LC/MS/MS analysis.

For Method M-073.1, the purified residues of all three analytes were derivatized with trifluoroacetic anhydride, and the resulting derivatized residues were analyzed by HPLC/FLD using a reverse phase C₈ column and an isocratic mobile phase of acetonitrile:water (85:15, v/v). For this method, the derivatized residues of avermectin B_{1a} and 8,9-Z avermectin B_{1a} are determined as a single component, and avermectin B_{1b} is determined separately. The validated LOQ for this method is 0.002 ppm for each analyte.

For Method Meth-192/Revision #2, no derivatization step was required. The purified residues were analyzed by LC/MS/MS using a reverse phase C₁₈ column with a mobile phase gradient of water:methanol (95:5, v/v) to methanol, each containing NH₄OAc. This method separately detects and quantifies all three analytes. The 895.5→751.5 m/z transition was used for detection and quantitation of avermectin B_{1a} and 8,9-Z avermectin B_{1a}, and the 881.2→737.0 m/z transition was used for detection and quantitation of avermectin B_{1b}. The validated LOQ for this method is 0.002 ppm for each analyte.

The above methods were validated in conjunction with the analysis of field trial samples. Control samples of each type of citrus fruit were fortified with avermectin B_{1a} at 0.002 and 0.033 ppm, avermectin B_{1b} at 0.002 ppm, and 8,9-Z avermectin B_{1a} at 0.002 and 0.033 ppm.

C. RESULTS AND DISCUSSION

The two methods (HPLC/FLD and LC/MS/MS) used for determining residues of avermectin B_{1a}, avermectin B_{1b}, and 8,9-Z avermectin B_{1a} in/on citrus fruits were adequately validated in conjunction with the analysis of the field trial samples. The LC/MS/MS method was used to analyze samples from three orange field trials, one grapefruit field trial, and one lemon field trial. All the other field trials were analyzed using the HPLC/FLD method. Concurrent method recoveries were within the acceptable range (70-120%) for all fortified samples analyzed using either method (Table C.1). For the HPLC/FLD method, the average recovery (±S.D.) from citrus fruits was 96 ± 7% for avermectin B_{1a}, 84 ± 8% for avermectin B_{1b}, and 93 ± 1% for 8,9-Z avermectin B_{1a}. For the LC/MS/MS method, the average recovery (±S.D.) from citrus fruits was 84 ± 9% for avermectin B_{1a} and 83 ± 10% for avermectin B_{1b}. Adequate sample chromatograms and example calculations were provided for both methods. Apparent residues of each analyte were <LOQ in/on all untreated samples. Concurrent fortification levels adequately bracketed field trial residue results.

Sample of citrus fruits were stored at -20°C for up to 5 months prior to extraction for analysis (Table C.2). Adequate storage stability data were submitted previously indicating that residues of avermectin B_{1a}, avermectin B_{1b}, and 8,9-Z avermectin B_{1a} are stable under frozen storage for up to 24 months in celery, strawberries, and tomatoes; 29 months in oranges, lemons, and grapefruit; and 35 months in pears (DP# 203373, G. J. Herndon, 3/29/95). These data adequately support the sample storage conditions and durations in the current field trials.



At 7 DAT, total residues of avermectin B_{1a} (avermectin B_{1a} + 8,9-Z avermectin B_{1a}) were <0.002-0.004 ppm in/on oranges, <0.002 ppm in/on grapefruits, and <0.002-0.006 ppm in/on lemons (Table C.3); total avermectin B_{1a} residues were \geq LOQ in only 3 out of 24 orange samples and 4 out of 10 lemon samples. In the samples analyzed by the HLPC/MS/MS method (6 orange samples, 2 grapefruit samples and 2 lemon samples), residues of 8,9-Z avermectin B_{1a} were <0.002 ppm in each sample. Residues of avermectin B_{1b} were also <0.002 ppm in/on all samples of oranges, grapefruits and lemons.

Following two foliar applications of abamectin (SC) at rates totaling 0.047-0.049 lb ai/A, total abamectin residues in/on citrus fruits harvested at 7 DAT were <0.004-0.006 ppm in/on oranges, <0.004 ppm in/on grapefruits, and <0.004-0.008 ppm in/on lemons. Average total residues were 0.004 ppm for oranges and grapefruits and 0.005 ppm for lemons (Table C.4). Total HAFT residues were 0.005 ppm for oranges, 0.004 ppm for grapefruits, and 0.007 ppm for lemons. There was no notable difference in residue values between the dilute and concentrated application volumes.

In both residue decline tests on lemons, total abamectin residues declined from 0.009-0.012 ppm at 0 DAT to <0.004 ppm by 10 DAT, indicating that abamectin residue decline at longer post-treatment intervals.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

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TABLE C.1. Summary of Concurrent Recoveries of Abamectin Residues from Citrus Fruits using HPLC/FLD and LC/MS/MS Methods.					
Analyte	Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean \pm Std. Dev. (%) ¹
HPLC/FLD Method No. M-073.1					
Avermectin B _{1a}	Oranges	0.002	3	93, 105, 96	99 \pm 5
		0.033	3	95, 105, 99	
	Grapefruit	0.002	2	93, 84	94 \pm 8
		0.033	2	103, 94	
	Lemons	0.002	3	93, 104, 85	96 \pm 8
		0.033	3	93, 105, 94	
	Citrus fruit	0.002-0.033	16	84-105	96 \pm 7
Avermectin B _{1b}	Oranges	0.002	3	85, 85, 95	88 \pm 6
	Grapefruit	0.002	2	76, 80	78
	Lemons	0.002	2	84, 94, 74	84 \pm 10
	Citrus fruit	0.002	7	74-95	84 \pm 8
8,9-Z avermectin B _{1a}	Oranges	0.002	1	94	93
		0.033	1	92	
	Grapefruit	0.002	1	94	94
		0.033	1	94	
	Lemons	0.002	1	94	93
		0.033	1	92	
	Citrus fruit	0.002-0.033	6	92-94	93 \pm 1
LC/MS/MS Morse Method No. Meth-192					
Avermectin B _{1a}	Oranges	0.002	2	79, 77	78 \pm 7
		0.033	2	88, 70	
	Grapefruit	0.002	1	89	94
		0.033	1	99	
	Lemons	0.002	1	88	86
		0.033	1	83	
	Citrus fruit	0.002-0.033	8	70-99	84 \pm 9
Avermectin B _{1b}	Oranges	0.002	2	70, 81	76
	Grapefruit	0.002	1	89	89
	Lemons	0.002	1	93	93
	Citrus fruit	0.002	4	70-93	83 \pm 10

¹ Standard deviations were calculated only for fortification levels with ≥ 3 samples.

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TABLE C.2. Summary of Storage Conditions.			
Matrix	Storage Temperature (°C)	Actual Storage Duration (months) ¹	Interval of Demonstrated Storage Stability (months) ²
Oranges	-20 ± 5	1-5	29 – citrus fruits
Grapefruits			
lemons			

¹ Interval from harvest to analysis. Extracts were stored 0-10 days prior to analysis.

² Storage stability data are available for oranges, lemons, and grapefruit stored for 29 months (DP# 203373, G. Herndon, 3/29/95).

TABLE C.3. Residue Data from Citrus Fruit Field Trials with Abamectin (SC).												
Trial ID (City, State; Year)	Zone	Crop; Variety	Matrix	TRT# ¹	Total Rate (lb ai/A)	PHI (days)	Abamectin Residues (ppm) ^{2,3}					
							B1 _a		B1 _b		Combined	
Oranges												
Haines City, FL 2007 E14FL078338	3	Orange; Hamlin	Fruit	2	0.047	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Groveland, FL 2007 E14FL078339	3	Orange; Hamlin	Fruit	3	0.046	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Bradenton, FL 2007 E16FL078340	3	Orange; Early Gold	Fruit	2	0.049	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Bradenton, FL 2007 E16FL078341	3	Orange; Hamlin	Fruit	3	0.046	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Bradenton, FL 2007 E16FL078342	3	Orange; Temple	Fruit	2	0.048	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Bradenton, FL 2007 E16FL078343	3	Orange; Valencia	Fruit	3	0.046	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
DeLeon Springs, FL 2007 E13FL078344	3	Orange; Valencia	Fruit	2	0.047	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
DeLeon Springs, FL 2007 E13FL078345	3	Orange; Navel	Fruit	3	0.046	7	<0.002	0.003	<0.002	<0.002	<0.004	0.005
Alamo, TX 2007 W08TX078350	6	Orange; Navel (N- 33)	Fruit	2	0.047	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Porterville, CA 2007 W32CA078352	10	Orange; Atwoods	Fruit	2	0.046	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Strathmore, CA 2007 W32CA07853	10	Orange; WA navel	Fruit	3	0.046	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Sanger, CA 2007 W30CA078354	10	Orange; Tsatsuma (mandarin)	Fruit	2	0.047	7	0.002	0.004	<0.002	<0.002	0.004	0.006



TABLE C.3. Residue Data from Citrus Fruit Field Trials with Abamectin (SC).

Trial ID (City, State; Year)	Zone	Crop; Variety	Matrix	TRT# ¹	Total Rate (lb ai/A)	PHI (days)	Abamectin Residues (ppm) ^{2,3}					
							BI _a		BI _b		Combined	
Grapefruit												
Groveland, FL 2007 E14FL078347	3	Grapefruit; Flame red	Fruit	2	0.046	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Haines City, FL 2007 E14FL078348	3	Grapefruit; Ruby red	Fruit	3	0.047	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Bradenton, FL 2007 E16FL078349	3	Grapefruit; Ruby red	Fruit	2	0.048	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Alamo, TX 2007 W08TX078351	6	Grapefruit; Rio red	Fruit	3	0.046	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Lindsay, CA 2007 W32CA078359	10	Grapefruit; Mellogold	Fruit	2	0.046	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Elderwood, CA 2007 W30CA078360	10	Grapefruit; Duncan	Fruit	3	0.046	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Lemons												
Fort Pierce, FL 2007 E15FL078346	3	Lemon, Bearss	Fruit	2	0.047	7	0.006	0.004	<0.002	<0.002	0.008	0.006
Porterville, CA 2007 W32CA078355	10	Lemon; Pryor	Fruit	2	0.046	0	0.007		<0.002		0.009	
						3	0.01		<0.002		0.012	
						5	0.005		<0.002		0.007	
						7	<0.002	0.006	<0.002	<0.002	<0.004	0.008
						10	<0.002		<0.002		<0.004	
Sanger, CA 2007 W30CA078356	10	Lemon; Lisbon 8A	Fruit	3	0.046	0	0.01		<0.002		0.012	
						3	0.008		<0.002		0.010	
						5	0.005		<0.002		0.007	
						7	<0.002	0.002	<0.002	<0.002	<0.004	0.004
						10	<0.002		<0.002		<0.004	
Elderwood, CA 2007 W30CA078357	10	Lemon; Lisbon	Fruit	2	0.046	7	<0.002	<0.002	<0.002	<0.002	<0.004	<0.004
Richgrove, CA 2007 W32CA078358	10	Lemon; Lisbon	Fruit	3	0.046	7	<0.002	0.002	<0.002	<0.002	<0.004	0.004

¹ Trt #2 used low volume or concentrated applications (10-97 gal/A) and Trt #3 used high volume or dilute applications (109-270 gal/A).

² The LOQ is 0.002 ppm for each analyte. Residue levels determined by the LC/MS/MS method are listed in italics; all other residues were determined using the HPLC/FLD method. Residues of B1_a include both avermectin B1_a and its 8,9-Z isomer.

³ Residues of the 8,9-Z isomer of avermectin B1_a were <LOQ in all samples analyzed by the LC/MS/MS method.

**TABLE C.4. Summary of Residue Data from Citrus fruit Field Trials with Abamectin (SC).**

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Application type	Total Abamectin Residues (ppm) ¹						
				n	Min.	Max.	HAFT ²	Median (STMdR)	Mean (STMR)	Std. Dev.
Oranges	0.046-0.049	7	Concentrated	14	<0.004	0.006	0.005	0.004	0.004	0.001
			Dilute	10	<0.004	0.005	0.005	0.004	0.004	<0.001
			Combined	24	<0.004	0.006	0.005	0.004	0.004	<0.001
Lemons	0.046-0.047	7	Concentrated	6	<0.004	0.008	0.007	0.005	0.006	0.002
			Dilute	4	<0.004	0.004	0.004	0.004	0.004	N/A
			Combined	10	<0.004	0.008	0.007	0.004	0.005	0.002
Grapefruits	0.046-0.048	7	Concentrated	8	<0.004	<0.004	0.004	0.004	0.004	N/A
			Dilute	4	<0.004	<0.004	0.004	0.004	0.004	N/A
			Combined	12	<0.004	<0.004	0.004	0.004	0.004	N/A

¹ Total residues include avermectin B_{1a} (avermectin B_{1a} + its 8,9-Z isomer) and avermectin B_{1b}. The LOQ is 0.002 ppm for each analyte for a combined LOQ of 0.004 ppm.

² HAFT = Highest Average Field Trial.

D. CONCLUSION

The submitted citrus field trials are adequate. An adequate number of orange, grapefruit and lemon field trials were conducted in the appropriate geographical regions. Residues of abamectin were determined using acceptable methods, and the sample storage conditions and durations are supported by adequate storage stability data. The field trial data support the use of two broadcast foliar applications of abamectin, formulated as a 0.7 lb ai/gal SC, on citrus fruits at up to 0.023 lb ai/A/application, for a total of 0.046 lb ai/A/season. The data also support a minimum RTI of 28 days and a minimum PHI of 7 days for citrus fruits. There was no noticeable difference in residue levels between the low and high volume applications, and residues were shown to decline with increasing post-treatment intervals.

E. REFERENCES

DP Number: 203373

Subject: Abamectin (Avermectin B₁) for Use in/on the Cucurbit Crop Group (Cucumbers, Melons and Squash). Evaluation of Analytical Methodology and Residue Data.

From: G. Herndon

To: G. LaRocca, L. Arrington and J. Smith

Dated: 3/29/95

MRIDs: 43203801 and 43228601

F. DOCUMENT TRACKING

RDI: Nancy Dodd (1/21/10); ChemTeam (1/21/10); Leung Cheng (1/21/10)

Petition Number: NA

DP#s: 364734 and 364737

PC Code: 122804



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: March 11, 2010

SUBJECT: **Abamectin.** Occupational and Residential Exposure Assessment for Proposed New Suspension Concentrate Formulation (Agri-Mek® SC, EPA Reg. No. 100-RGLR) on Various Crops with Established Tolerances.

PC Code: 122804	DP Barcode: 364734
Decision Number: 407406	Registration Number: 100-RGLR
Petition Number: NA	Regulatory Action: Section 3
Risk Assessment Type: Single Chemical	Case Number: NA
TXR Number: NA	CAS Number: 71751-41-2
MRID Numbers: NA	40CFR: §180.449

FROM: Nancy J. Tsaur, Chemist
Risk Assessment Branch 3
Health Effects Division (7509P)

THROUGH: Barry O'Keefe, Senior Biologist, ORE Team Leader
Risk Assessment Branch 3
Health Effects Division (7509P)

TO: John Hebert/Thomas Harris, Risk Management Team 07
Insecticide/Rodenticide Branch
Registration Division (7505P)

The Registration Division (RD) requested that the Health Effects Division (HED) conduct an occupational exposure and risk assessment for the newly proposed suspension concentrate (SC) formulation of abamectin for use on various crops with existing tolerances, including: almonds and walnuts, apples, avocados, celeriac, citrus, cotton, cucurbits, fruiting vegetables, grapes, herbs (except chives), hops, leafy vegetables, mint, pears, plums and prunes, and potatoes.

Conclusion: The proposed application rates and agricultural sites have been previously assessed for an emulsifiable concentrate (EC) formulation. New occupational assessments are not needed because the units of exposure and the application rates remain unchanged between the proposed SC product and the existing EC product. A safety factor of 3X has been applied to account for the steepness of the dose-response curve in several studies and the severity of effects (death) seen at the slightly higher dose level. The need for a new risk assessment to address exposure and risk from food and drinking water pathways will be addressed in a separate memorandum. A restricted entry interval (REI) of 12 hours on the Agri-Mek SC label is in compliance with the

Worker Protection Standard (WPS) for Agricultural Pesticides for all crops except grapes. Based on the postapplication assessment, grapes require a 4-day REI. This document was reviewed by HED Exposure Science Advisory Council on 03/11/2010.

1.0 INTRODUCTION

A new aqueous suspension concentrate (SC) formulation (EPA Reg. No. 100-RGLR) is being proposed by Syngenta Crop Protection, Inc. (Syngenta) for use on various crops with existing tolerances. This new end use product (EP), Agri-Mek® SC (Agri-Mek SC), contains the active ingredient (ai) abamectin—a mixture of avermectin B₁ [a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-*O*-demethyl avermectin A₁) and less than or equal to 20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A₁)] and its delta-8,9-isomer. As a natural fermentation product of the soil bacterium *Streptomyces avermitilis*, abamectin is an insecticide/miticide used to control mites, leafminers, and other insects in commercially important crops. Abamectin acts as an insecticide by interfering with the nervous system of the insect, causing paralysis.

2.0 HAZARD CHARACTERIZATION

The results of available toxicity studies with single or repeated dosing indicate that the main target organ is the nervous system and that decreased body weight is also one of the most frequent findings. Oncogenicity and mutagenicity studies provide no indication that abamectin is carcinogenic or mutagenic. Neurotoxicity and developmental effects are detected in multiple studies and species of test animals. Increased susceptibility was seen in prenatal developmental toxicity studies in mice and rabbits. Susceptibility was also shown in reproductive toxicity and developmental neurotoxicity studies in rats where decreased pup body weight was seen in the absence of maternal toxicity. In the same studies, more severe effects (death and morbid sacrifice) occurred at higher doses. Because the dose/response curve is very steep with severe effects following repeated exposures, an additional 3X FQPA Safety Factor has been applied to ensure protection against decreased body weight seen in the rat reproduction and neurotoxicity studies. With respect to acute toxic effects, neither a steep dose/response response curve nor severe effects were observed. Therefore, an additional FQPA Safety Factor is not needed to ensure protection against effects seen in the dog (mydriasis) and the rat (increased incidence of foot splay) following a single dose. Thus, the regulatory decision ensures protection against neurotoxic effects seen in the dog and rat and reduced pup body weight seen in the rat reproduction and developmental neurotoxicity studies, which were the most sensitive acute and chronic endpoints, respectively, observed in the toxicology data base.

It should be noted that the uncertainties associated with the FQPA Safety factor are also applicable to occupational workers. Therefore, an additional 3X uncertainty factor has been applied to occupational populations. The RAB3 Risk Assessment Team evaluated the entire toxicity database of abamectin and determined that the additional 3X safety factor was needed to address residual concerns of all risk assessments other than acute dietary (N. Dodd, DP#362615, 03/11/2009).

The toxicity endpoints and the PoDs for various exposure scenarios are presented below in Table 1.

Table 1. Summary of Toxicity Endpoints and Points of Departure for Abamectin Occupational Risk Assessment.

Exposure/ Scenarios	Point of Departure	Uncertainty/ Safety Factor	RFD, PAD, LOC*	Study and Toxicological Effects
Acute Dietary (General population, including infants and children and	NOAEL = 0.5 mg/kg/day	UF _A = 10X UF _H = 10X	aRfD = 0.005 mg/kg/day	Acute neurotoxicity study in rats. LOAEL = 1.5 based on increased incidence of foot splay. 12-Week dose-range finding study in dogs. LOAEL = 1.0 mg/kg/day based on mydriasis seen 1-5 times during the first week of treatment.
Chronic Dietary (All populations)	NOAEL = 0.12 mg/kg/day	UF _A = 10X UF _H = 10X SF = 3X	cPAD = 0.0004 mg/kg/day	Combined data from three reproduction studies and two developmental neurotoxicity studies. LOAEL = 0.2 mg/kg/day based on decreased pup body weight in pups at 0.2 mg/kg/day.
Short-Term and Intermediate Term Incidental Oral	NOAEL = 0.12 mg/kg/day	UF _A = 10X UF _H = 10X SF = 3X	LOC: MOE = 300	Combined data from three reproduction studies and two developmental neurotoxicity studies. LOAEL = 0.2 mg/kg/day based on decreased pup body weight in pups.
Dermal (All Durations)	NOAEL = 0.12 mg/kg/day	UF _A = 10X UF _H = 10X SF = 3X	LOC: MOE = 300	Combined data from three reproduction studies and two developmental neurotoxicity studies. LOAEL = 0.2 mg/kg/day based on decreased pup body weight in pups.
Inhalation (All durations)	NOAEL = 0.12 mg/kg/day	UF _A = 10X UF _H = 10X SF = 3X	LOC: MOE = 300	Combined data from three reproduction studies and two developmental neurotoxicity studies. LOAEL = 0.2 mg/kg/day based on decreased pup body weight in pups.
Cancer (oral, dermal, inhalation)	Classification: Not likely to be carcinogenic to human based on the absence of significant increase in tumor incidence in two adequate rodent carcinogenicity studies.			

Point of Departure (PoD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

* Level of Concern (LOC): For occupational exposure risk assessments, the uncertainty factor is 300X (10X for interspecies extrapolation; 10X for intraspecies variations; and 3X for the steepness of the dose-response curve in several studies and the severity of effects (death) seen at the slightly higher dose level).

For determining overall risk, the dermal and inhalation hazards are based on the same study and, therefore, on the same effects of concern. Thus, the dermal and inhalation exposures/risks may be combined (added together) and compared to the same NOAEL as above. A 60 kg body weight was used for all adult exposure calculations because the endpoint is based on developmental/fetal effects (decreased pup body weight). Chronic exposures are not expected.

Available dermal toxicity studies were conducted using formulated product and were not considered appropriate for use in risk assessment. No appropriate inhalation toxicity studies are available. The results from a dermal absorption study in monkeys demonstrate that < 1% of an applied dose of abamectin is absorbed. A 1% dermal absorption factor and a 100% inhalation absorption factor were used in the route-to-route extrapolation.

Table 2 presents a summary of the acute toxicity of technical abamectin.

Table 2. Acute Toxicity of Abamectin Technical.				
Guideline No.	Study Type	MRID No.	Results	Tox. Category
870.1100	Acute Oral - rat (sesame oil vehicle)	006894	LD ₅₀ = 13.6 mg/kg	I
870.1100	Acute Oral - rat (methyl cellulose vehicle)	45607202	LD ₅₀ =214-232 mg/kg	II
870.1200	Acute Dermal - rabbit	0025978	LD ₅₀ = 2000 mg/kg	III
870.1300	Acute Inhalation - rat	45623501	LC ₅₀ <0.21 mg/L (nose only)	I
870.2400	Primary Eye Irritation	45063501	not an irritant	IV
870.2500	Primary Skin Irritation	41123904	slight irritation	III
870.2600	Dermal Sensitization	-	negative in Buehler	Negative
870-6200a	Acute Neurotoxicity	none	none	none

3.0 PROPOSED USE PATTERN

The EC formulation, Agri-Mek® 0.15 EC (Agri-Mek EC), is currently registered for use on various crops including: almonds and walnuts, apples, avocados, celeriac, citrus, cotton, cucurbits, fruiting vegetables, grapes, herbs (except chives), hops, leafy vegetables, mint, pears, plums and prunes, and potatoes. The new formulation, Agri-Mek SC, is intended for use on these same crops with the same use rates. Table 3 summarizes the comparison of use rates between the existing EC formulation and the proposed SC formulation.

Table 3. Comparison of Label Use Rates of EC and SC Formulations.				
Crop(s)	Registered: Agri-Mek EC EPA Reg. No. 100-898 max application rate (density = 0.15 lb ai/gal)		Proposed: Agri-Mek SC EPA Reg. No. 100-RGLR max application rate (density = 0.7 lb ai/gal)	
	fl oz/A	lb ai/A	fl oz/A	lb ai/A
Almonds and Walnuts	20	0.023	4.25	0.023

Table 3. Comparison of Label Use Rates of EC and SC Formulations.

Crop(s)	<i>Registered: Agri-Mek EC</i> EPA Reg. No. 100-898 max application rate (density = 0.15 lb ai/gal)		<i>Proposed: Agri-Mek SC</i> EPA Reg. No. 100-RGLR max application rate (density = 0.7 lb ai/gal)	
	fl oz/A	lb ai/A	fl oz/A	lb ai/A
Apples	20	0.023	4.25	0.023
Avocados	20	0.023	4.25	0.023
Celeriac	16	0.019	3.5	0.019
Citrus	20	0.023	4.25	0.023
Cotton	16	0.019	3.5	0.019
Cucurbits	16	0.019	3.5	0.019
Fruiting Vegetables	16	0.019	3.5	0.019
Grapes	16	0.019	3.5	0.019
Herbs (except Chives)	16	0.019	3.5	0.019
Hops	16	0.019	3.5	0.019
Leafy Vegetables	16	0.019	3.5	0.019
Mint	12	0.014	2.5	0.014
Pears	20	0.023	4.25	0.023
Plums and Prunes	20	0.023	4.25	0.023
Potatoes	16	0.019	3.5	0.019

4.0 OCCUPATIONAL EXPOSURE

Based on application rate and label information, exposure is expected to occur for short- and intermediate-term durations. Chronic exposure is not expected for the proposed use patterns. The EC formulation, Agri-Mek EC (EPA Reg. No. 100-898), has been previously assessed at the same use rates currently proposed for the SC formulation, as shown below in Table 4. **New occupational assessments are not needed because the units of exposure and the application rates remain unchanged between the proposed SC product and the existing EC product.** The margins of exposure (MOEs) for all crops, except cotton, ranged from 630 to 9200. With the additional 3X safety factor (and an LOC of 300), all MOEs are not of concern.

Table 4. Summary of Previous Assessments for Agri-Mek EC (EPA Reg. No. 100-898).

Crops	Proposed SC Rate (lb ai/A)	DP Barcode(s)	Date	Reviewer	Comments
Almonds and Walnuts	0.023	344809	12/04/2008	Jack Arthur	Assessed at 0.023 lb ai/A (CG 14).
Apples*	0.023	---	---	---	Not specifically assessed.
Avocados	0.023	306906	10/29/2004	Jack Arthur	Assessed at 0.023 lb ai/A.
Celeriac	0.019	344809	12/04/2008	Jack Arthur	Assessed at 0.019 lb ai/A (CG 4).
Citrus	0.023	347959	10/29/2008	Jack Arthur	Assessed at 0.023 lb ai/A (CG 10).
Cotton**	0.019	---	---	---	Not specifically assessed.
Cucurbits	0.019	344809	12/04/2008	Jack Arthur	Assessed at 0.019 lb ai/A (CG 9).
Fruiting Vegetables	0.019	306906	10/29/2004	Jack Arthur	Assessed at 0.019 lb ai/A.
		344809	12/04/2008	Jack Arthur	Assessed at 0.019 lb ai/A (CG 12).
Grapes*	0.019	---	---	---	Not specifically assessed.
Herbs (except Chives)	0.019	306906	10/29/2004	Jack Arthur	Assessed at 0.019 lb ai/A.
Hops*	0.019	---	---	---	Not specifically assessed.
Leafy Vegetables	0.019	306906	10/29/2004	Jack Arthur	Assessed at 0.019 lb ai/A.
		344809	12/04/2008	Jack Arthur	Assessed at 0.019 lb ai/A (CG 4).
Mint	0.014	306906	10/29/2004	Jack Arthur	Assessed at 0.019 lb ai/A.

Table 4. Summary of Previous Assessments for Agri-Mek EC (EPA Reg. No. 100-898).

Crops	Proposed SC Rate (lb ai/A)	DP Barcode(s)	Date	Reviewer	Comments
Pears*	0.023	---	---	---	Not specifically assessed.
Plums and Prunes	0.023	306906 344809	10/29/2004 12/04/2008	Jack Arthur Jack Arthur	Assessed at 0.023 lb ai/A. Assessed at 0.023 lb ai/A (CG 12).
Potatoes	0.019	344809	12/04/2008	Jack Arthur	Assessed at 0.019 lb ai/A (CG 1C).

* Apples, grapes, hops, and pears have not been specifically assessed in previous assessments. However, the use patterns and scenarios associated with these crops are covered by other crop assessments (i.e., the use patterns of Agri-Mek SC on apples, grapes, hops, and pears are all identical to the previously assessed use pattern of Agri-Mek EC on almonds and walnuts; and the previously assessed use rates of Agri-Mek EC are equal to or higher than those proposed for Agri-Mek SC on apples, grapes, hops, and pears).

** Upon review of previous risk assessments, HED noted that the risk estimate for mixing/loading of abamectin for aerial application on cotton of both products, Agri-Mek EC and Agri-Mek SC, exceeds HED's LOC of 300 (MOE = 260). With respect to cotton, the MOE is driven by the inhalation exposure for mixing/loading abamectin for aerial application. Aerial application is calculated with the assumption that up to 1200 acres may be treated in one day. The accepted unit exposure (UE) from the Pesticide Handlers Exposure Database (PHED) for mixing/loading liquids for aerial application is 1.2 µg/lb ai handled. Results for mixing/loading for aerial application to cotton based on PHED unit exposure values indicate a risk of concern. However, additional data currently under development by the Agricultural Handlers Exposure Task Force (AHETF) of which Syngenta is a member, indicate that inhalation exposures are lower than predicted using PHED and result in no risks of concern. The AHETF data are considered to be more representative of modern cultural practices and of higher quality than PHED. Given the overestimate of exposure, HED believes that the MOE of 260 will provide a sufficient margin of protection for the cotton mixer/loader.

The required personal protective equipment (PPE) includes: long-sleeved shirt, long pants, chemical-resistant gloves made of waterproof material, shoes plus socks, and an organic vapor (OV) respirator. The new SC formulation acute inhalation toxicity study indicates a higher toxicity than the EC formulation based on a greater percent ai (8% compared to 2%). Thus, Agri-Mek SC is classified as Toxicity Category II which, according to the Worker Protection Standard (WPS) for Agricultural Pesticides, requires a respirator. Based on a review of the registrant's request for a waiver, HED has determined that a waiver for the WPS respirator may be granted for both the mixer/loader and the applicator scenarios for Agri-Mek SC and thus, the PPE requirement for an OV respirator may be removed from the label. The recommendation for waiving the WPS PPE requirement was granted on a case-by-case basis and specifically applies to Agri-Mek SC (DP#373491, N. Tsaur, 02/24/2010).

5.0 OCCUPATIONAL POSTAPPLICATION EXPOSURE AND RISK

Occupational postapplication exposures and risk estimates for Agri-Mek EC have been previously assessed for all proposed crops except for apples, cotton, grapes, hops, and pears. The short- and intermediate-term MOEs for postapplication exposure of all previously assessed crops on the day of treatment ("day 0"), range from 580 to 7000. Since the proposed application

rates and use patterns for Agri-Mek SC are the same as those registered for Agri-Mek EC and the proposed Agri-Mek SC maximum application rates and postapplication worker activities for apples and pears are identical to the rates and activities of plums and prunes on the Agri-Mek EC label, new postapplication assessments are not needed for all proposed crops except for cotton, grapes, and hops. For cotton, grapes, and hops, there is potential for dermal postapplication exposure to scouts, harvesters, and other field workers following foliar application.

5.1 Data and Assumptions for Postapplication Exposure Scenarios

Since no chemical-specific postapplication data were submitted in support of this registration action, dermal exposures during postapplication activities were estimated using dermal transfer coefficients (TCs) from the ExpoSAC SOP No. 003.1: Agricultural Transfer Coefficients, August 2000, and the following assumptions:

- Application Rate = 0.019 lb ai/A for cotton, grapes, and hops
- Exposure Duration = 8 hours per day
- Body Weight = 60 kg for average adult
- Dermal Absorption = 1% for short-term and intermediate-term
- Fraction of ai retained on foliage is assumed to be 20% (0.2) on day zero for agricultural crops (default values established by HED ExpoSAC).
- The initial fraction of ai retained is assumed to further dissipate at the rate of 10% (0.1) per day on following days (default values established by HED ExpoSAC).

HED's postapplication exposure estimates are based on surrogate data. The TCs are considered to be central tendency. Maximum application rates were used in this assessment. Overall, the postapplication risks are characterized as being central to high-end estimates. The postapplication activity scenarios along with respective TCs are summarized below in Table 6.

Proposed Crop	Policy Crop Group Category	Exposure Potential	Transfer Coefficients (cm ² /hr)	Activities
Cotton	Field, low	High	2,500	Hand Harvesting
		Medium	1,500	Irrigation, Scouting, Hand Weeding
		Low	100	Irrigation, Scouting, Hand Weeding
Grapes	Vine/Trellis	Very High	10,000	Girdling, Cane Turning, Tying
		High	5,000	Hand Harvesting, Hand Pruning, Thinning
		Medium	1,000	Scouting
		Low	500	Hand Weeding, Scouting, Hedging
Hops	Bunch/Bundle	High	2,000	Hand Harvesting, Mechanical Harvesting, Stripping, Training
		Medium	1,300	Scouting
		Low	100	Irrigation, Weeding, Scouting, Hand Weeding

Equations/Calculations: The following equations were used to calculate risks for workers performing postapplication activities:

$$DFR_t (\mu\text{g}/\text{cm}^2) = AR (\text{lb ai}/\text{acre}) \times F \times (1-D)^t \times 4.54\text{E}8 \mu\text{g}/\text{lb} \times 2.47\text{E}-8 \text{ acre}/\text{cm}^2$$

Where: DFR_t = dislodgeable foliage residue on day "t" ($\mu\text{g}/\text{cm}^2$),
 AR = application rate (lb ai/acre),
 F = fraction of ai retained on foliage (unitless), and
 D = fraction of residue that dissipates daily (unitless).

and

$$\text{Daily dermal dose}_t (\text{mg}/\text{kg}\cdot\text{day}) = \frac{DFR_t (\mu\text{g}/\text{cm}^2) \times 1\text{E}-3 \text{ mg}/\mu\text{g} \times TC (\text{cm}^2/\text{hr}) \times DA \times ET (\text{hrs})}{BW (\text{kg})}$$

Where: t = number of days after application day (days),
 DFR_t = dislodgeable foliage residue on day "t" ($\mu\text{g}/\text{cm}^2$),
 TC = transfer coefficient (cm^2/hr),
 DA = dermal absorption factor (unitless),
 ET = exposure time (hr/day), and
 BW = body weight (kg).

5.2 Agricultural Postapplication Exposure and Risk

For cotton and hops, postapplication exposure and risk estimates do not exceed HED's LOC (MOEs > 300). For grapes, the calculations indicate that MOEs of 300 are achieved on Day 0 for all grape scenarios, except very high exposure activities on grapes, for which an REI of 4 days was calculated. Based on this exposure assessment, there were calculated postapplication occupational risks of concern for workers conducting specific activities working in grape vineyards treated with abamectin. These specific tasks are grape girdling, cane turning, and tying. Therefore, for these very high exposure activities, an REI of 4 days is required to reach an MOE of 300. **To mitigate the postapplication risk to reentry works performing these tasks, it is recommended that the *interim* REI of 12 hours be increased to 4 days.** This activity-specific REI of 4 days should not pose a hardship for the grower. Typically, 1) grape tying and cane turning occur 30 days or more after a fungicide application, and 2) cane girdling is now primarily replaced by trunk girdling, which is a much lower exposure activity. Postapplication activities for grapes represent the worst-case scenario. The postapplication exposure and risk estimates associated with cotton, grapes, and hops are summarized below in Table 7.

Table 7. Summary of Estimated Margins of Exposure.				
DAT ^a	DFR ^b (µg/cm ²)	TC ^c (cm ² /hr)	Activity	MOE ^d
				Short-/Int-Term
Cotton				
0	0.043	100	Irrigation, Scouting, Hand Weeding	21,000
0		1,500	Irrigation, Scouting, Hand Weeding	1,400
0		2,500	Hand Harvesting	840
Grapes				
0	0.043	500	Hand Weeding, Scouting, Hedging	4,200
0		1,000	Scouting	2,100
0		5,000	Hand Harvesting, Hand Pruning, Thinning	420
0	0.038 0.035 0.031 0.028	10,000	Grape Girdling, Cane Turning, Tying	210
1				240
2				260
3				290
4				320

Table 7. Summary of Estimated Margins of Exposure.				
DAT ^a	DFR ^b (µg/cm ²)	TC ^c (cm ² /hr)	Activity	MOE ^d
				Short-/Int-Term
Hops				
0	0.043	100	Irrigation, Weeding, Scouting, Hand Weeding	21,000
0		1,300	Scouting	1,600
0		2,000	Hand Harvesting, Mechanical Harvesting, Stripping, Training	1,000

a DAT = Days after treatment needed to reach the LOC of 300; DAT 0 = the day of treatment, after sprays have dried; assumed to be approximately 12 hours.

b DFR (µg/cm²) = Application rate (lb ai/A) x F x (1- daily dissipation rate)¹ x CF (4.54E+8 µg/lb) x CF (2.47E-8 A/cm²) x 20% DFR after initial treatment.

c Transfer coefficients and associated activities from ExpoSAC SOP No. 003.1 "Agricultural Transfer Coefficients," 8/17/2000.

d MOE = NOAEL/Daily Dose; (Short-Term and Intermediate-Term Dermal NOAEL = 0.12 mg/kg/day).

5.3 Restricted Entry Interval (REI)

The proposed label for Agri-Mek SC has a 12-hour REI. The technical material is classified as Toxicity Category III for Acute Dermal and Primary Skin Irritation, Toxicity Category IV for eye irritation, and is not a dermal sensitizer. Under the WPS for Agricultural Pesticides, a 12-hr REI is required for chemicals classified under Toxicity Categories III and IV. **Therefore, the interim REI of 12 hours on the Agri-Mek SC label is in compliance with the WPS for all crops except grapes. Based on the postapplication assessment, grapes require a 4-day REI.**

Note to PM: The currently registered product, Agri-Mek EC (EPA Reg. No. 100-898), should also require a 4-day REI for grapes.

6.0 RESIDENTIAL (NON-OCCUPATIONAL) EXPOSURE

This document presents the assessment of proposed agricultural uses of abamectin. No residential uses are being requested at this time; therefore, no residential handler exposure and risk assessment has been conducted in this document.

While no residential uses are proposed in the current petition for the Agri-Mek SC formulation, there are residential uses currently registered for other end-use products of abamectin. Since residential uses of abamectin are currently registered, short- and intermediate-term exposures may occur to adults from handling the pesticide. Residential handler exposures have been previously assessed for two uses which are considered to represent the reasonable high-end residential exposure potential: 1) granular baits used to treat lawns; and 2) indoor crack and crevice dust products (DP#362615, N. Dodd, 03/03/2009). **The MOEs for all residential scenarios are greater than the LOC of 300 and, therefore, are not of concern.**

7.0 SPRAY DRIFT

Spray drift is always a potential source of exposure to residents nearby to spraying operations. This is particularly the case with aerial application but, to a lesser extent, could also be a potential source of exposure from the groundboom application methods additionally employed for abamectin. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices, and State Lead Agencies for pesticide regulation and other parties to develop the best

spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling. The Agency has completed its evaluation of the new database submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast, and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate.

8.0 REVIEW OF HUMAN RESEARCH

This risk assessment relies in part on data from PHED and AHETF studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies have been reviewed and have been determined to be ethical.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: February 25, 2010

SUBJECT: **Abamectin.** Review of Syngenta Waiver Request of WPS Respirator Requirement for Two Abamectin End-Use Products Pending EPA Registration (EPA Reg. Nos. 100-RGLR and 100-RGLN).

PC Code: 122804	DP Barcode: 373491, 373492
Decision No.: NA	Registration No.: 100-RGLR, 100-RGLN
Petition No.: NA	Regulatory Action: Waiver Request Review
Assessment Type: NA	Case No.: NA
TXR No.: NA	CAS No.: 71751-41-2
MRID No.: 47976701, 47976702	40 CFR: §180.449

FROM: Nancy J. Tsaur, Chemist
Risk Assessment Branch 3
Health Effects Division (7509P)

THROUGH: Barry O'Keefe, Senior Biologist, ORE Team Leader
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Health Effects Division (7509P)

TO: Thomas Harris, Risk Manager
Insecticide/Rodenticide Branch
Registration Division (7505P)

1.0 ACTION REQUESTED

Syngenta Crop Protection, Inc. (Syngenta) has submitted a request to waive the Worker Protection Standard (WPS) respirator requirement for two abamectin end-use products (EPs) currently pending EPA registration: Agri-Mek® SC (Reg. No. 100-RGLR) and Agri-Flex™ Insecticide/Miticicide (Reg. No. 100-RGLN). The Health Effects Division (HED) has been requested to evaluate this submission and determine whether or not to recommend for approval of the waiver. In support of their request, Syngenta also submitted a study to support the request (*A Laboratory Simulation to Determine the Level of Abamectin in the Mixer/Loader's Breathing Zone While Pouring Concentrated Formulations of Abamectin (A15368D and A15543C) from the Commercial Container into a Mix Tank*, 12/21/2009, MRID 47976702). This request was reviewed by the HED Exposure Science Advisory Council (ExpoSAC) on 02/25/2010.

2.0 CONCLUSIONS

HED has determined that a waiver for the WPS respirator may be granted for both the mixer/loader and the applicator scenarios for both EPs, Agri-Mek® SC (Agri-Mek SC) and Agri-Flex™ Insecticide/Miticide (Agri-Flex). This decision was made based on an analysis of the impurities in the EPs and comparisons of the acute inhalation toxicity studies among the SC formulations, the technical product formulation, and the emulsifiable concentrate (EC) formulation. HED believes the supporting study (MRID 47976702) does not provide clear and convincing evidence that there is negligible inhalation exposure to abamectin during the mixing/loading process. However, HED believes that the Pesticide Handlers Exposure Database (PHED) best represents the occupational exposure scenarios requested for both SC products. Thus, the required personal protective equipment (PPE) can be established based on risk estimates and exposure scenarios as opposed to the WPS requirements. Despite the recommendation to waive the respirator requirement, it should be noted that there may be specific use patterns which require respirators based on risk assessment estimates calculated using various unit exposures from such databases as PHED. This recommendation for waiving the WPS PPE requirement is granted on a case-by-case basis and only applies to the products discussed in this document.

3.0 RESULTS/DISCUSSION

3.1 Mixer/Loader Respirator Requirement

The Registration Division (RD) is responsible for ensuring that the PPE listed on the label is in compliance with the WPS for Agricultural Pesticides. The minimum level of PPE for occupational handlers (mixing, loading, and applying) is based on the acute toxicity for a proposed product. Agri-Mek SC and Agri-Flex are both classified as Acute Toxicity Category II for acute inhalation (DP#364731 and DP#364736, respectively). Based on this classification, both EPs require respirators during mixing/loading activities.

Syngenta's Proposal

Syngenta has submitted a proposal to waive the WPS respirator requirement for two abamectin EPs currently pending EPA registration: Agri-Mek SC and Agri-Flex. Syngenta's main line of reasoning for a waiver request is that the requirement for respirators is based on the assumptions that (1) the products will volatilize into the breathing zone and (2) the acute inhalation study is an appropriate model for the potential inhalation toxicity to the handler. Thus, according to Syngenta, if these two assumptions can be disproved, the requirement for respirators should be waived.

To disprove the first assumption, Syngenta cited HED SOP 2002.01 *Guidance: Waiver Criteria for Multiple-Exposure Inhalation Toxicity Studies*: "waivers will be considered for non-volatile active ingredients which are not aerosolized (i.e. generated as mists, fogs, dust, smoke, fumes), heated, evaporated, or otherwise made inhalable as a gas or vapor." Based on this guidance, Syngenta concluded that "according to the EPA's criteria for acute inhalation toxicity testing, the lack of volatility of abamectin and the lack of worker exposure to abamectin suggest that acute

inhalation toxicity testing may not have been needed for either of these products.” To indicate lack of vaporization and volatilization into the breathing zone, Syngenta has referred to abamectin’s extremely low vapor pressure ($<5.0 \times 10^{-9}$ kPa at 25°C).

To disprove the second assumption that the acute inhalation study is an appropriate model for the potential inhalation toxicity to the handler, Syngenta has also provided the results from a mechanized laboratory study. This study (MRID 47976702) was conducted to simulate a mixer/loader pouring of both products into a mix tank “to determine the potential for abamectin to volatilize and be available for respiration in the worker breathing zone.”

HED's Response

SOP 2002.01 *Criteria 2* defines “non-volatile” active ingredients as $<1 \times 10^{-5}$ kPa (7.5×10^{-5} mmHg) for indoor uses and $<1 \times 10^{-4}$ kPa (7.5×10^{-4} mmHg) for outdoor uses at 20-30°C. Since the abamectin technical vapor pressure is $<5.0 \times 10^{-9}$ kPa at 25°C, HED agrees that abamectin can be classified as a “non-volatile” active ingredient. Regardless, volatility is not the single concern when assessing inhalation toxicity. The Agency recently presented scientific issues associated with field volatilization of conventional pesticides at a Science Advisory Panel (SAP) meeting (12/01/2009–12/04/2009, available at <http://www.epa.gov/scipoly/SAP/meetings/2009/120109meeting.html>). Work done for the volatilization SOP indicates inhalation toxicity is typically under-represented when using oral toxicity studies to select an inhalation endpoint; sometimes by several orders of magnitude. Thus, the potential inhalation risk is likely to be higher when compared against an oral endpoint.

Additionally, the referenced document for waiver request criteria, SOP 2002.01, is irrelevant because the guidance refers to multiple-exposure inhalation toxicity studies, not acute inhalation toxicity studies. Thus, the authority to grant a waiver under SOP 2002.01 is not applicable to this situation. Syngenta also highlighted that the 40 CFR § 158.500 states that the EPA requires an acute inhalation toxicity study for a technical or EP “if the product consists of, or under conditions of use will result in, a respirable material (e.g., gas, vapor, aerosol, or particulate).” Based on the fact that occupational handlers are likely to be exposed to respirable material of abamectin during mixing/loading, HED confirms that an acute inhalation study would have been required.

With respect to the pouring study submitted by Syngenta, HED has concluded that the study only provides two replicates of air sampling and does not properly simulate a realistic exposure scenario. The majority of registered pesticides do not represent volatilization concerns. The main concern for the respiratory protection required by WPS is not based on the volatilization. Rather, the main concerns of WPS protection are based upon the droplets and the aerosolization caused by the action of the handler mixing/loading.

Furthermore, unit exposures for such inhalation scenarios already exist in PHED. In accordance with HED ExpoSAC policy, exposure data from PHED Version 1.1, as presented in PHED Surrogate Exposure Guide (8/98), is used to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available.

In summary, HED agrees with Syngenta that the product will not volatilize into the breathing zone, but notes that volatilization is not the sole contributor to inhalation exposure (there is potential for exposure through inhalation of droplets and aerosol particles due to the nature of mixing/loading). HED believes that the acute inhalation study is an appropriate model for the potential inhalation toxicity to the occupational handler and that the submitted pouring study (MRID 47946702) is not relevant for quantitative risk assessment purposes. HED also believes that using PHED data is the appropriate approach to represent occupational handler exposures as the PHED unit exposure values are protective of the occupational handler's potential exposure to droplets and aerosolization caused by the action of mixing/loading. **HED recommends waiving the requirement for a respirator based on the acute inhalation Toxicity Category for mixer/loaders for both EPs, Agri-Mek SC and Agri-Flex. This recommendation for waiving the mixer/loader respirator requirement is granted on a case-by-case basis and applies only to these two EPs.**

3.2 Applicator Respirator Requirement

As with the mixer/loader scenario, RD is responsible for ensuring that the PPE listed on the label is in compliance with WPS for applicators. Since the minimum level of PPE for occupational handlers is based on the acute toxicity for an EP and both products are classified as Acute Toxicity Category II for acute inhalation (DP#364731 and DP#364736), both EP require respirators during application activities.

Syngenta's Proposal

Syngenta has highlighted that the acute inhalation toxicity of these products is based on testing with the undiluted product and that WPS assumes that the acute inhalation toxicity of the product when diluted and sprayed is equal to the acute inhalation toxicity of the product in its concentrated form.

HED's Response

HED agrees that the dilution of these products prior to application results in a reduction of the acute inhalation toxicity hazard. The decision to account for the dilution is risk-based (i.e., the dilution of the product will reduce the exposure and thus, reduce the risk). **Since the applicator is only handling the diluted product, HED recommends waiving the requirement for a respirator in the specific scenario for applicators of both EPs, Agri-Mek SC and Agri-Flex. This recommendation for waiving the applicator respirator is unique and applies only to these two EPs.**

3.3 Comparison of Acute Inhalation Toxicities

The exposure parameters and the incidences of rat mortality based on the 4-hour limit dose acute inhalation toxicity testing at each exposure level are summarized in Tables 1-4 below.

Table 1. Abamectin Technical Acute Inhalation Toxicity (EPA Reg. No. 100-1259).			
abamectin = 91.5% purity			
Exposure (mg/L)	Mortality		
	Males	Females	Total
0.029	-	0/5	0/10
0.0518	0/5	2/5	2/10

Acute toxicity based on review DP#334558.

Table 2. Agri-Mek 0.15 EC Acute Inhalation Toxicity (EPA Reg. No. 100-898).			
abamectin = 1.82% abamectin concentration = 0.057 g/L			
Exposure (mg/L)	Mortality		
	Males	Females	Total
5.04*	0/5	0/5	0/10

Acute toxicity based on review DP#310270.

* Toxicity based on lack of deaths at limit dose.

Table 3. Agri-Mek SC Acute Inhalation Toxicity (EPA Reg. No. 100-RGLR).			
abamectin = 8% abamectin concentration = 80.8 g/L			
Exposure (mg/L)	Mortality		
	Males	Females	Total
0.054	1/5	1/5	2/10
0.53	5/5	5/5	10/10

Acute toxicity based on review DP#364731.

Table 4. Agri-Flex Acute Inhalation Toxicity (EPA Reg. No. 100-RGLN).			
abamectin = 3% (thiamethoxam = 13.9%) abamectin concentration = 34.9 g/L			
Exposure (mg/L)	Mortality		
	Males	Females	Total
0.054	1/5	1/5	2/10
0.53	5/5	5/5	10/10

Acute toxicity based on review DP#364736.

Based on these findings, the ai (Abamectin Technical II) and both SC formulations (Agri-Mek SC and Agri-Flex) are currently classified as Toxicity Category II acute inhalation hazards, indicating that the LC₅₀ values determined in the acute (4-hour) inhalation tests were between 0.05 and 0.50 mg/L. While the registered EC formulation (Agri-Mek 0.15 EC) is classified as Toxicity Category IV, indicating that the LC₅₀ values determined in the acute (4-hour) inhalation tests were greater than 2.0 mg/L. Table 5 shows the category classifications based on exposures.

Table 5. Toxicity Category Classifications Based on Exposures.	
LC ₅₀ Range(mg/L)	Toxicity Category
< 0.05	I
> 0.05 to < 0.50	II
> 0.50 to < 2.0	III
> 2.0	IV

The acute inhalation studies show a direct correlation between the percentage of abamectin and the acute inhalation hazard. Table 6 shows a comparison of abamectin products and their respective acute inhalation toxicity results. Table 7 summarizes the results of all acute toxicity testing for the technical ingredients and the end use products.

Table 6. Comparison of Abamectin Products and Acute Inhalation Toxicity Results.				
Product Name	% Abamectin	LC ₅₀ Exposures (mg/L)	Acute Inhalation Toxicity Category	Product Density (lb ai/gallon)
Agri-Mek 0.15 EC	2	> 5.04	IV	0.15
Agri-Flex	3	> 0.054 to < 0.53	II	0.277
Agri-Mek SC	8	> 0.054 to < 0.53	II	0.7
Technical II	91.5	> 0.0518	I*	92% technical

* The study in MRID 46945406 indicates this test material is borderline between Category I and II in terms of inhalation toxicity. The registrant's proposed label indicates ("Fatal if inhaled.") a Toxicity Category I classification, and HED finds this acceptable. The 40% mortality rate in females exposed to 0.0518 mg/L indicates an approximate 31.7% probability that the LC₅₀ value for this sex is below 0.0518 mg/L.

Table 7. Summary of Acute Toxicity Testing.				
Toxicity Test	Technical II 91.5%	Agri-Mek 0.15 EC 2%	Agri-Mek SC 8%	Agri-Flex 3% (MAI w/ Thiamethoxam)
Acute Oral	II	III	II*	III
Acute Dermal	II	IV	III	IV
Acute Inhalation	I**	IV	II	II
Primary Eye Irritation	IV	IV	IV	III
Primary Skin Irritation	IV	IV	IV	IV
Dermal Sensitization	negative	negative	negative	negative

* **Bolded** numbers indicate an increase in toxicological concern as compared with the currently registered product, Agri-Mek 0.15 EC.

** The study in MRID 46945406 indicates this test material is borderline between Category I and II in terms of inhalation toxicity. The registrant's proposed label indicates ("Fatal if inhaled.") a Toxicity Category I classification, and HED finds this acceptable. The 40% mortality rate in females exposed to 0.0518 mg/L indicates an approximate 31.7% probability that the LC₅₀ value for this sex is below 0.0518 mg/L.

4.0 REFERENCES

A Laboratory Simulation to Determine the Level of Abamectin in the Mixer/Loader's Breathing Zone While Pouring Concentrated Formulations of Abamectin (A15368D and A15543C) from the Commercial Container into a Mix Tank. MRID#47976702, M.R. Witcher, 12/15/2009.

Abamectin and Thiamethoxam Request for Waiver of WPS Respirator Requirement for End-Use Products Pending EPA Registration – 2009 Waiver Request. MRID#47976701, C. Brinkley, 01/05/2010.

Acute Toxicity Memorandum: Abamectin Technical II, DP#334558, B. Backus, 06/18/2007.

Acute Toxicity Memorandum: Agri-Flex Miticide/Insecticide, DP#364736, E. McAndrew, 02/03/2010.

Acute Toxicity Memorandum: Agri-Mek 0.15 EC, DP#310270, E. McAndrew, 11/24/2004.

Acute Toxicity Memorandum: Agri-Mek SC, DP#364731, E. McAndrew, 02/03/2010.

Guidance: Waiver Criteria for Multiple-Exposure Inhalation Toxicity Studies. M.J. Stasikowski, 08/15/2002.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: 2/18/10

MEMORANDUM

SUBJECT: **Abamectin.** Human Health Risk Assessment Analysis for Proposed Use as: (1) a Soybean Seed Treatment (Non-food); and (2) Bridging Studies from Emulsifiable Concentrate (EC) to Suspension Concentrate (SC) Formulations to Support SC Use on Almonds, Walnuts, Apples, Pears, Avocadoes, Celeriac, Citrus Fruit, Cotton, Cucurbit Vegetables, Fruiting Vegetables, Grapes, Herbs (except Chives), Hops, Leafy Vegetables, Mint, Plums, Prunes, and Potatoes.

PC Code: 122804

Decision Nos.: 407406, 407407

Petition No.: NA

Risk Assessment Type: Single Chemical/Aggregate

TXR No.: NA

MRID No.: NA

DP Barcodes: 374426, 374427

Registration Nos.: 100-1204, 100-RGLR, 100-RGLN

Regulatory Action: Section 3 Registration/Product Registration

Case No.: NA

CAS Nos.: 65195-55-3, 71751-41-2

40 CFR: 180.449

FROM: Nancy Dodd, Chemist and Risk Assessor
Nancy Tsaur, Chemist
Whang Phang, Toxicologist
Risk Assessment Branch III
Health Effects Division (7509P)

THROUGH: Paula Deschamp, Branch Chief
Risk Assessment Branch III
Health Effects Division (7509P)

TO: Venus Eagle/Thomas Harris, RM#1
Insecticide-Rodenticide Branch
Registration Division (7505P)

The purpose of this memorandum is to document that a human health aggregate risk assessment for abamectin is not needed for the proposed use as a soybean seed treatment (non-food) or for bridging from emulsifiable concentrate (EC) to suspension concentrate (SC) formulations to support SC use on almonds, walnuts, apples, pears, avocadoes, celeriac, citrus fruit, cotton,

cucurbit vegetables, fruiting vegetables, grapes, herbs (except chives), hops, leafy vegetables, mint, plums, prunes, and potatoes. A summary of the proposed new uses/products is provided in the following table:

Product and % Active Ingredient	Reg. No.	DP Barcode
Avicta 500 FS	100-1204	365440
Agri-Flex SC	100-RGLN	364737
Agri-Mek SC	100-RGLR	364734

There are no changes to abamectin dietary exposure from food and water and no changes to residential exposure resulting from these new proposed uses of abamectin. The potential for increased abamectin exposure/risk to occupational workers related to these new uses will be addressed in separate documents.

The need for exposure/risk assessments for thiamethoxam, a co-formulation in the proposed new SC product (100-RGLN) will be addressed in a separate document.